# EXHIBIT U

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SEVEN YEAR DATA FOR TEN YEAR PROLENE™ STUDY: ERF 85-219

This report contains a summary of IR, IV, GPC, OM and SEM data supporting this study.

**IR and IR Microspectroscopy** (D.Burkley)

IR examinations were done for all explants at all sites to verify the suture identity for each explant. For all explanted sutures recovered from all 6 sites for every dog in this study, IR data showed each suture to be correctly identified.

IR microspectroscopy was used to examine cracked areas in ETHILON, Novafil and PROLENE™ explants. IR spectra obtained for cracked PROLENE specimens (Figure A) showed possible evidence of slight oxidation (a broadened weak absorbance at about 1650 cm-1). IR spectra obtained for cracked areas of ETHILON and Novafil did not differ from uncracked areas (Figures B and C), but expected IR absorbances for oxidation would be masked by the strong carbonyl absorbances normally observed for these sutures. Figures D and E show pictures of the areas examined by IR microspectroscopy for ETHILON and Novafil.

**IV and GPC** (E.Muse)

Gel Permeation Chromatography (GPC) was run on PROLENE sutures explanted from dogs after seven years. The GPC data was compared to data from a current 4/0 PROLENE suture. The results indicate that there was no significant difference in molecular weight between the 4/0 PROLENE control and the seven year explants.

The following PROLENE explant samples were analyzed:

Dog 1995 - site 3 (SR33853)
Dog 2007 - sites 1 and 6 (SR34003)
Dog 2008 - site 2 (SR34066)
Dog 2019 - sites 2 and 3 (SR34180)

The GPC analysis was run on the Waters 150C GPC at 140°C using 1,2,4 trichlorobenzene as a mobile phase with Waters GPC columns. The instrument was calibrated with polypropylene standards.

Inherent Viscosity (IV) was determined on ETHILON™ and Novafil sutures explanted from dogs after seven years. The IV data[1] was compared to IV data from one and two year explants. The following results were found:

1) No significant differences were seen in IV values after one and two years.
2) Seven year IV values ranged from 75% to 93% of the one and two year IV values for ETHILON sutures.
3) Seven year IV values ranged from 75% to 90% of the one and two year values for Novafil.

The dog explant samples examined were from duplicate sites on four dogs for each time period (one, two and seven years). The IV data was determined using concentrations of 0.1 dl/g with HFIP as a solvent at 25°C.

**OPTICAL MICROSCOPY and SCANNING ELECTRON MICROSCOPY** (E.Lindemann)

**Conclusions**

- The 7 year in-vivo results generally substantiated the five year findings. They also closely correspond to the observations of explanted sutures from the dog that died prematurely after 6 years and 10.5 month implantation time.

- Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in- house made suture in terms of cracking.

- Of the eight explanted ETHILON sutures all showed heavy cracking and, in many cases, abrasion of the dyed surface layer. A decrease in the suture diameter was apparent in several cases.

- Cracks were not found in the seven Novafil explants. However a few longitudinal scratches probably due to mechanical damage and one longitudinal crack were observed.

**Introduction**

In November 1985 twenty-four dogs had been implanted with sets of ETHILON, PROLENE, PVDF and Novafil sutures for a ten year study. In 1990, after five years, explants from 5 beagle dogs were described in " TEN YEAR IN-VIVO STUDY SCANNING ELECTRON MICROSCOPY FIVE YEAR REPORT" by Elke Lindemann. The next explantation, after 7 years, was to start in June 1992. However, after 6 years and 10.5 months dog #1995 died prematurely. The microscopical examination of those explants was described in " TEN YEAR IN-VIVO STUDY: SCANNING ELECTRON AND LIGHT MICROSCOPY INTERIM REPORT ON DOG #1995 AFTER 6 YEARS, 10.5 MONTH, SR# 33788 and are included in the conclusion section of this report. In June of 1992 after 7 years, sutures were explanted from another set of 4 dogs. This report presents the results of the light and scanning electron microscopical examination of those explants.

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[1]SR33853, SR34003, SR34066, SR34180

**Experimental**

Four dogs had been implanted in November 1985 with the following 5-0 sutures:

| | Site 1 | Site 2 | Site 3 | Site 4 | Site 5 | Site 6 |
|---|---|---|---|---|---|---|
| Dog 2001 | PVDF | ETHILON | Novafil | PROLENE | PROLENE | Novafil |
| Dog 2007 | PROLENE | Novafil | ETHILON | PVDF | PVDF | PROLENE |
| Dog 2019 | Novafil | PROLENE | PROLENE | PVDF | ETHILON | ETHILON |
| Dog 2008 | ETHILON | PROLENE | Novafil | PVDF | ETHILON | PVDF |

Starting in June of this year the above dogs were sacrificed in weekly intervals. Approximately 20cm long sections of the explanted sutures were received in microscopy in glass vials which were kept refrigerated until they were examined.

Also the explanted LC 100 clip with about 2cm of each suture bundle was delivered in the same vial. The clip and the attached sutures were still deeply embedded in the surrounding tissue. These 'not cleaned' sutures were supposed to answer the question whether the process of cleaning and tissue removal might be responsible for an observed cracking. The primary concern of this study was however to examine the long pieces of explanted suture. Most of these specimens were still surrounded with some tissue, fortunately at a level low enough not to obscure examination in the light microscope under transmitted light. It was possible to examine the embedded PROLENE suture where the cracking of the suture was seen through the tissue. For this reason and time constrains the clip-attached sutures were not examined at this time.

To show that the drying and coating with a metal under vacuum, necessary for SEM examination, did not introduce cracking and other surface defects each strand of each long suture was 100% inspected in the Olympus Light Microscope in water. Oil, the usual medium for light microscopical inspection, was not chosen for this examination in order to eliminate surface changes during sample preparation. To cut down on lensing effects of the curved suture, the samples were photographed in polarized light using a 10x phase condenser with an ordinary transmitted light 20x objective (a 20x phase condenser was not available). The light diffraction introduced by the phase condenser was enough to allow an easier focusing at the focal plane of the largest diameter. Photomicrographs were prepared at 285x of areas which showed surface changes.

Strands of the suture including the above areas were then prepared for SEM observation in the JEOL JSM 840 AII by coating them under vacuum with gold to provide an electron conductive surface. Photomicrographs were prepared at 500x magnification.

**Results**

**1) LM and SEM of PROLENE suture explants from seven implantation site.**

In Figure 1A through 1D one area per site from each of the four dogs is shown in transmitted light. Out of seven sites cracking was found on PROLENE sutures from three sites. Notice the cracks observable through the still adhering tissue in Figure 1A in the suture from site 2.

In Figure 1 and 2 SEM views of areas are shown after most of the tissue had been carefully removed. Again out of seven sites sutures from three sites had areas which showed cracking.

**2) LM and SEM of ETHILON suture explants from six implantation sites.**

In Figure 3A through 3C sutures are shown from six different sites. Transmitted light allowed visualization of the differences between the intact dyed surface layer and the underlying colorless layers of the suture. In Figure 3A site 5 and Figure 3C site 3 the colorless area had not only lost its dyed surface layer but was abraded to such a degree that a decrease in suture diameter was found.

In Figures 3 and 4 the cracking and abrasion on sutures from all six sites, as observed with the SEM, is shown. Here also the decrease in diameter is particularly dramatic in Figure 3 site 1.

**3) LM and SEM of PVDF suture explants from six implantation sites.**

Figure 5A through 5C show six sites of PVDF explants as seen with the light microscope. Notice the intact surface on all the sutures.

In Figures 5 and 6 the SEM examination of the PVDF sutures is shown. Only on the suture from one site (Figure 6 site 6) some cracks are found. The surfaces of the sutures from the other five sites show some striations which could be mechanical damage, otherwise the surfaces look intact. The contaminant on the site 4 (Figure 5) suture is tissue which had not been removed completely.

**4) LM and SEM of Novafil suture explants from five implantation sites.**

Figure 7A through 7C show the Novafil sutures as observed with the light microscope. All surfaces from all sites look undamaged. Figure 7 and 8 show the SEM examination of these sutures. A few longitudinal scratches and cracks were found, see sites 1,2,3 (Figure 7,8). Also on the site 2 suture (Figure 8) still adhering tissue is found.

**5) Degradation dependency on implantation site**

To probe the question as to whether one implantation site might be more or less stressful towards the suture, a comparison was made of the six sites.

| | Site 1 | Site 2 | Site 3 | Site 4 | Site 5 | Site 6 |
|---|---|---|---|---|---|---|
| Dog 1995 | ETHILON cracks | PVDF | PROLENE cracks | Novafil | Novafil cracks | ETHILON cracks |
| Dog 2001 | PVDF | ETHILON cracks | Novafil | PROLENE | PROLENE cracks | Novafil |
| Dog 2007 | PROLENE | Novafil scratch | ETHILON cracks | PVDF | PVDF | PROLENE cracks |
| Dog 2019 | Novafil scratch | PROLENE | PROLENE | PVDF | ETHILON cracks | ETHILON cracks |
| Dog 2008 | ETHILON cracks | PROLENE cracks | Novafil cracks | PVDF | ETHILON cracks | PVDF cracks |

The only site, in the 5 dogs of this study, from which sutures were explanted that showed no surface damage was site 4. However, of those five sutures three were PVDF and one was Novafil. Those are the sutures that showed only marginal surface changes in this study. Therefore this observation can be discounted.

Elke Lindemann

Eugene P. Muse

Daniel F. Burkley

Attachment

7YEAR.DFB

Figure A - Comparison IR Spectra of Cracked and Non-cracked Regions of PROLENE (SR33788)

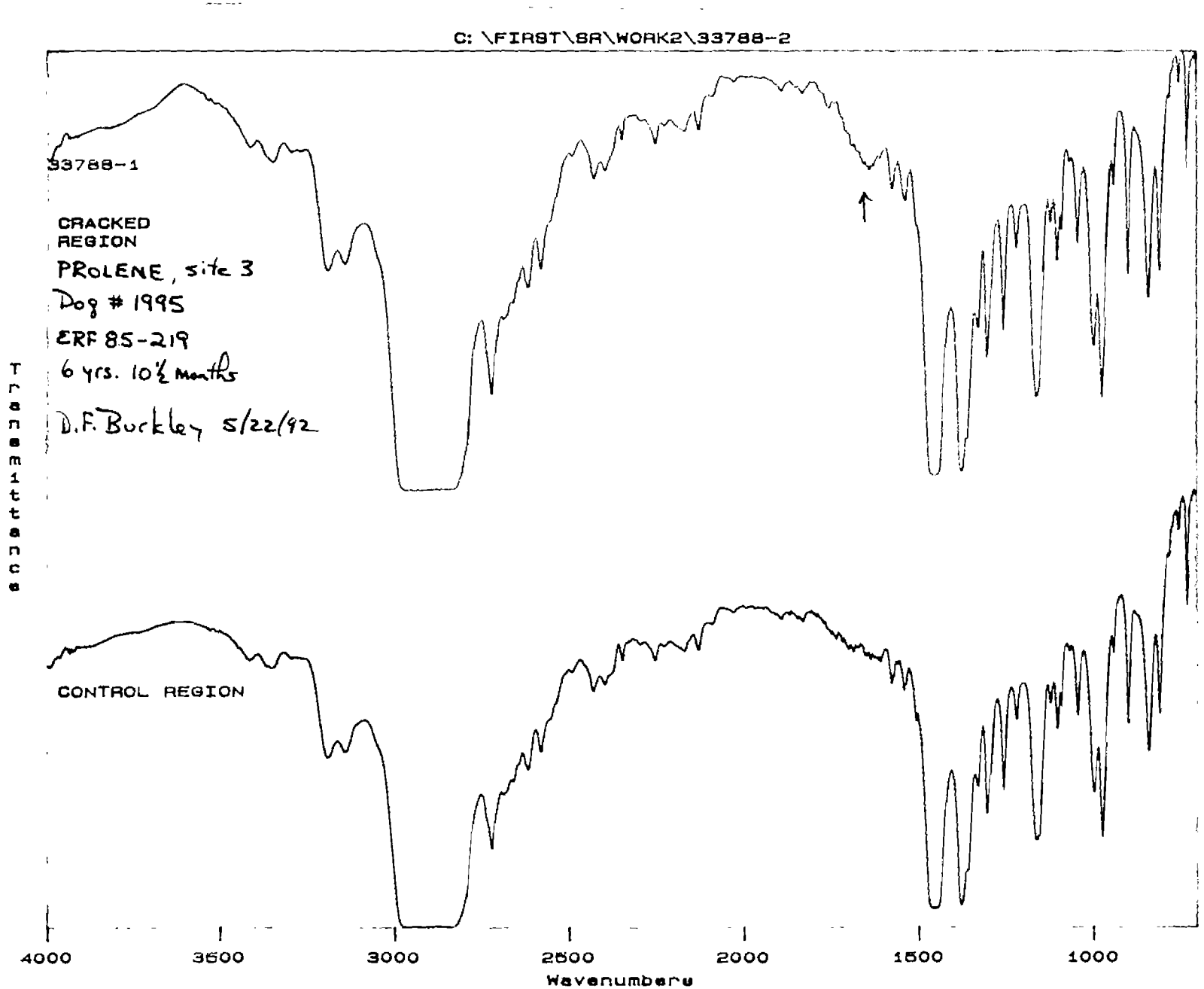


Figure B - Comparison IR Spectra of Cracked and Non-cracked Regions of ETHILON (SR33853)

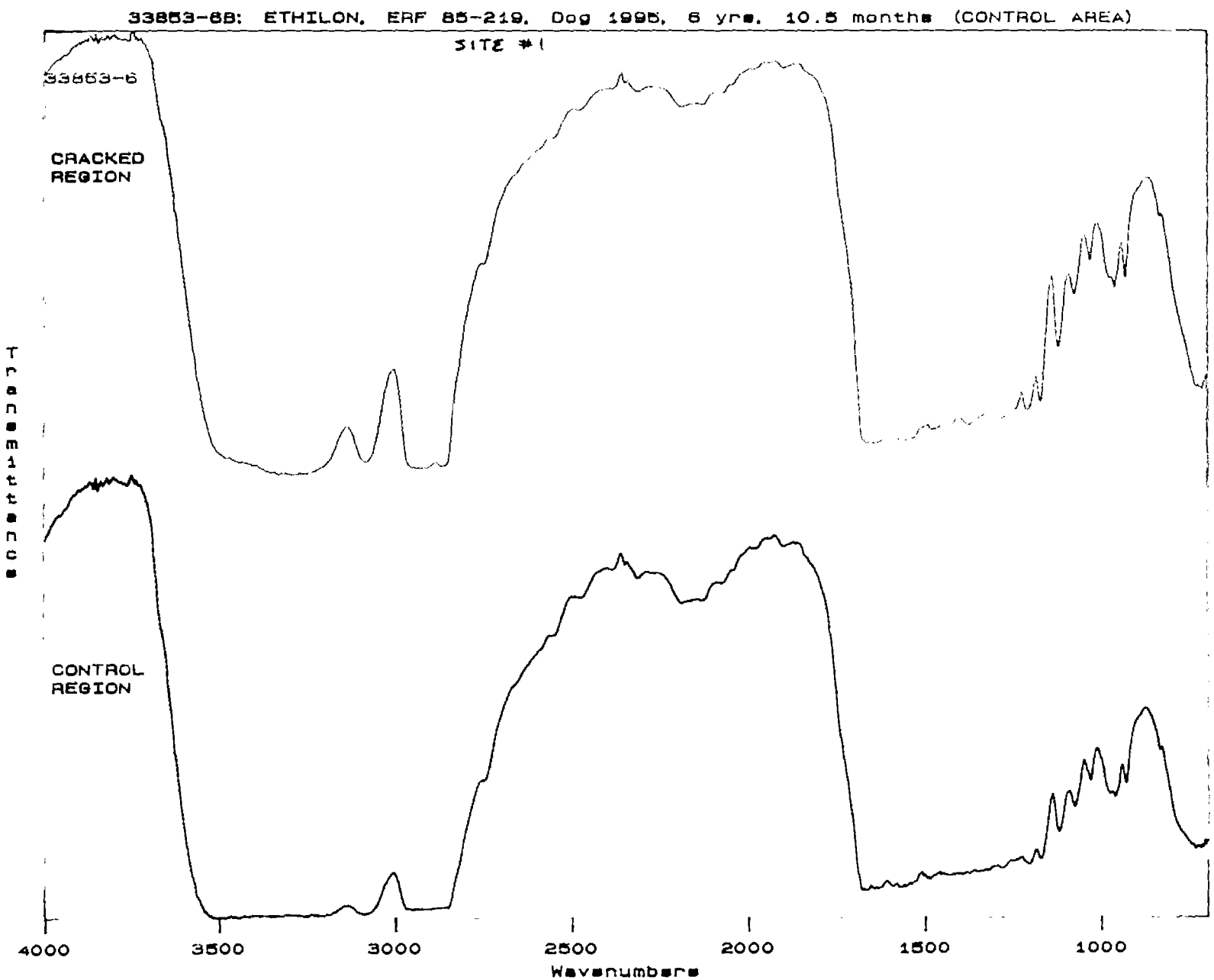
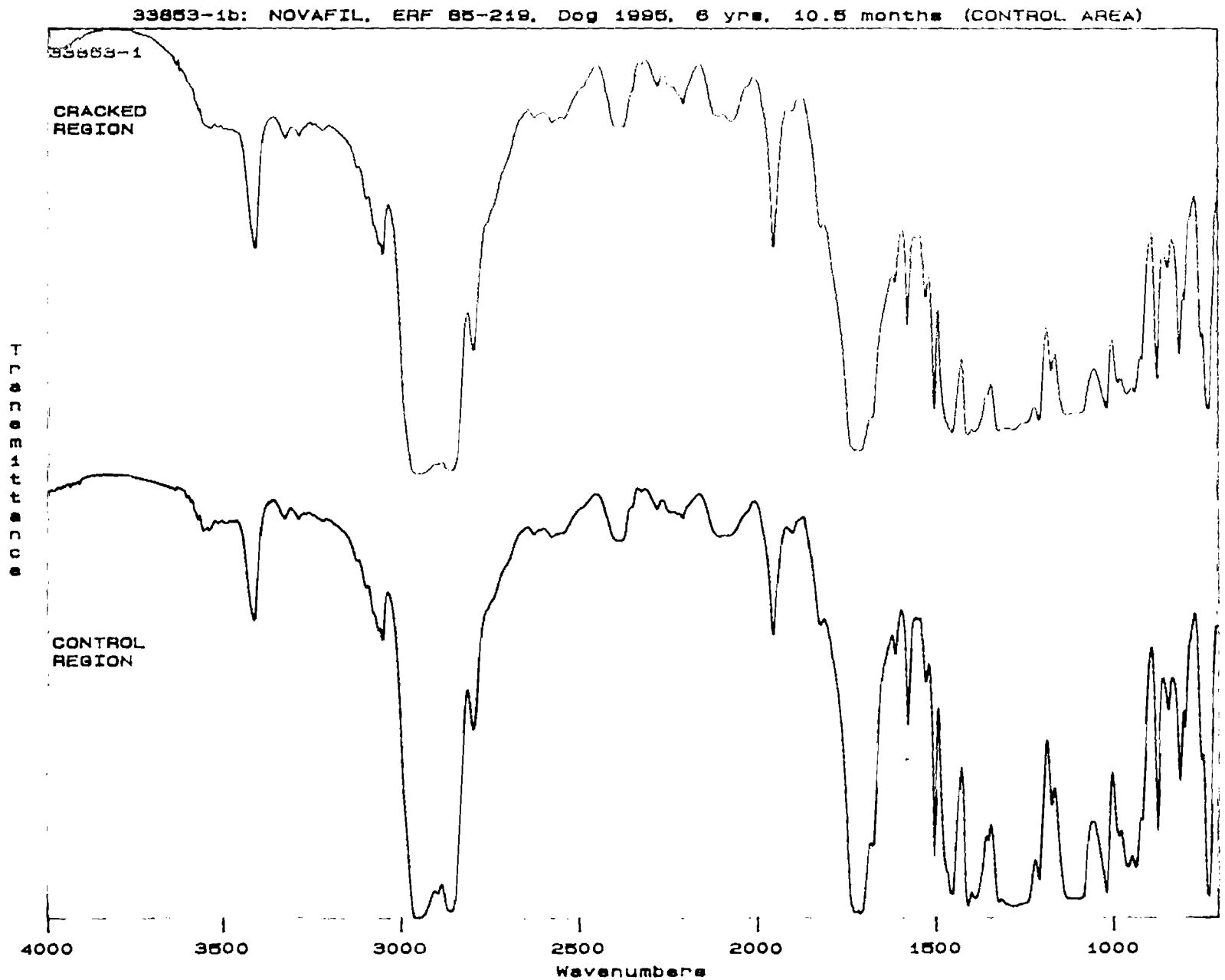


Figure C - Comparison IR Spectra of Cracked and Non-cracked Regions of Novafil (SR33853)



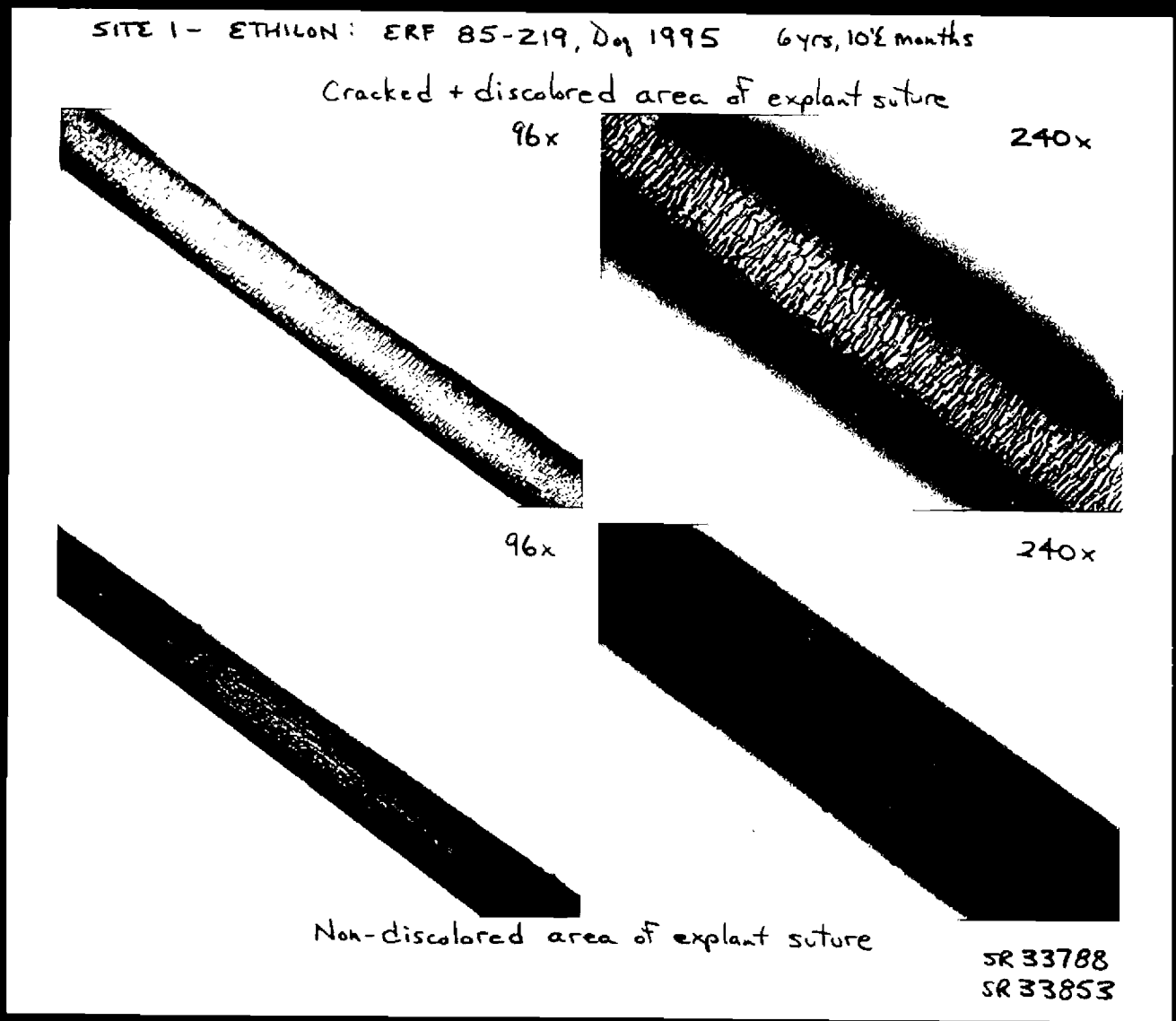



Figure D - Comparison Pictures of Cracked and Non-cracked Regions of ETHILON (SR33853)

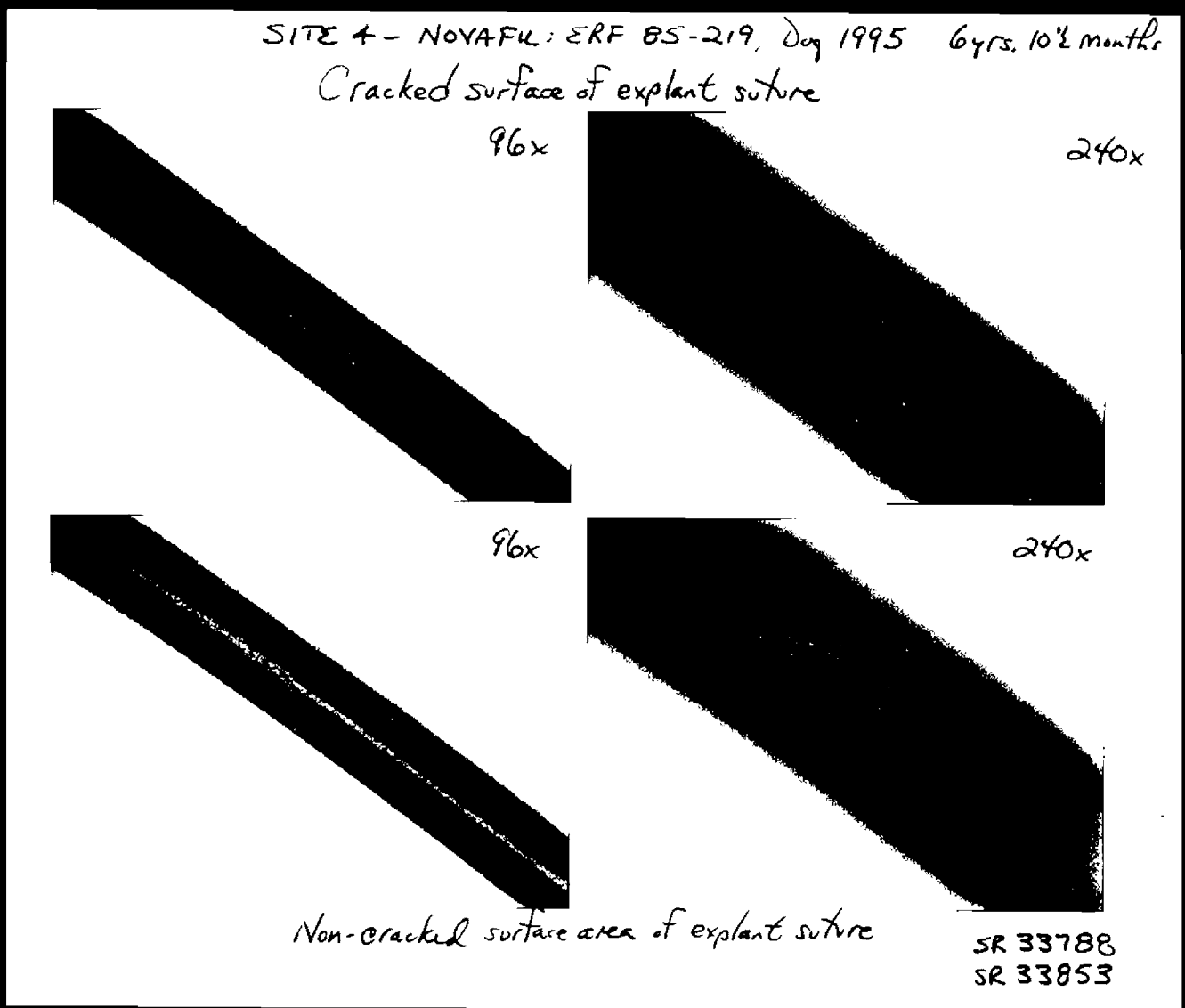
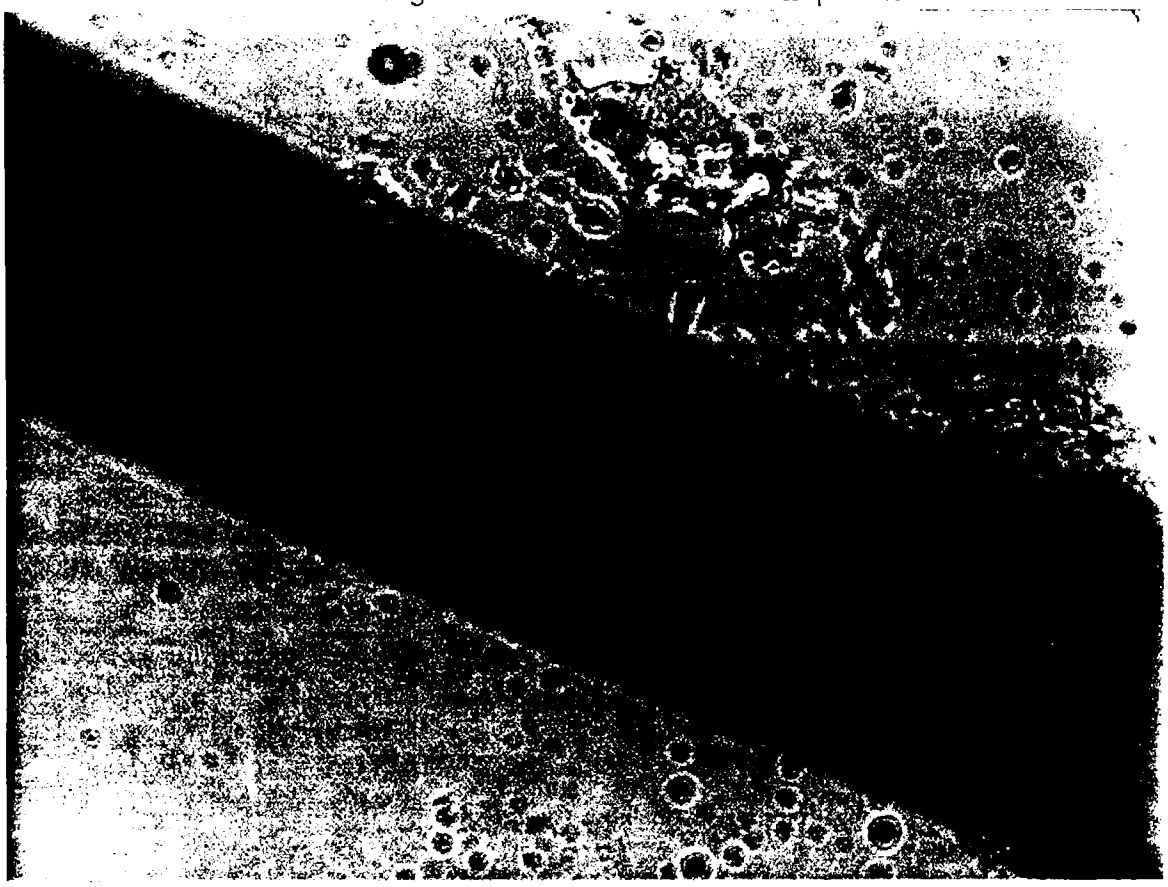
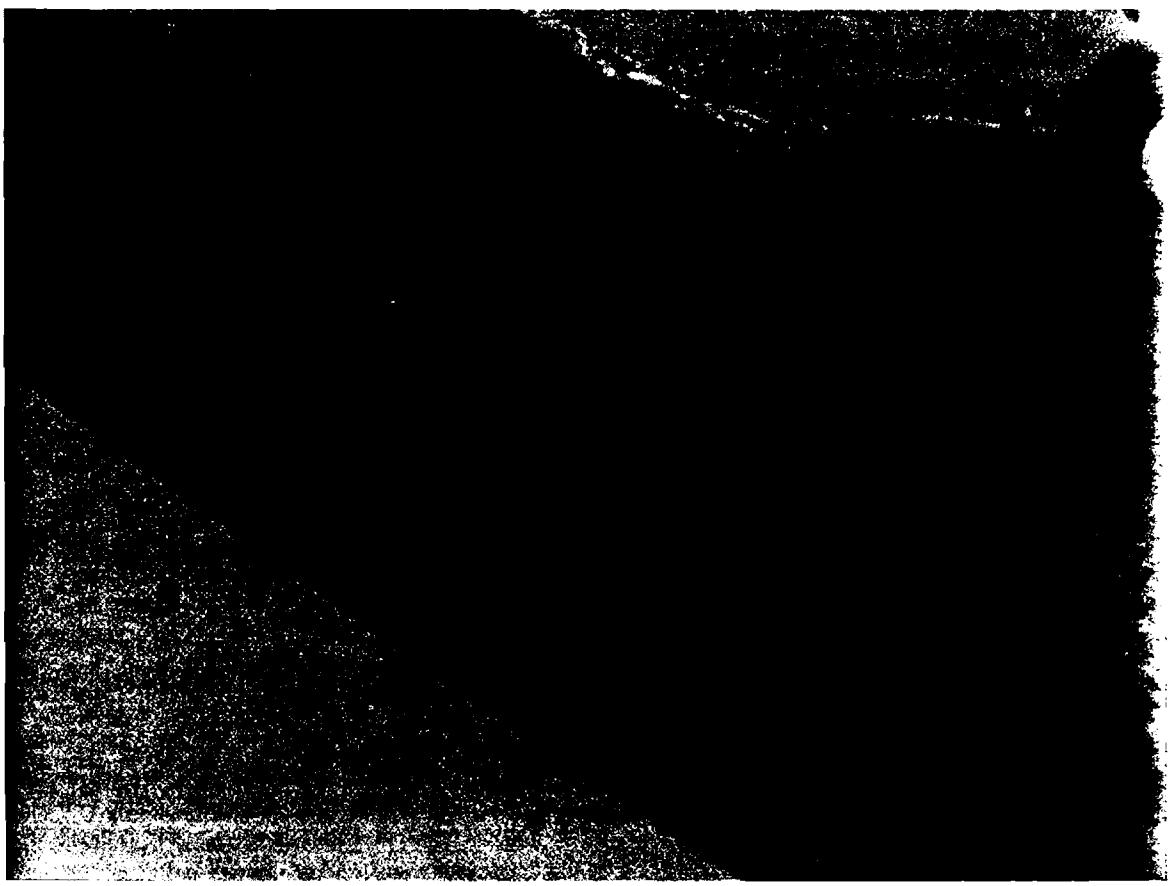



Figure E - Comparison Pictures of Cracked and Non-cracked Regions of Novafil (SR 33853)

Figure 1A 7 Year Prolene Explants



dog 2001 site 5



dog 2008 site 2

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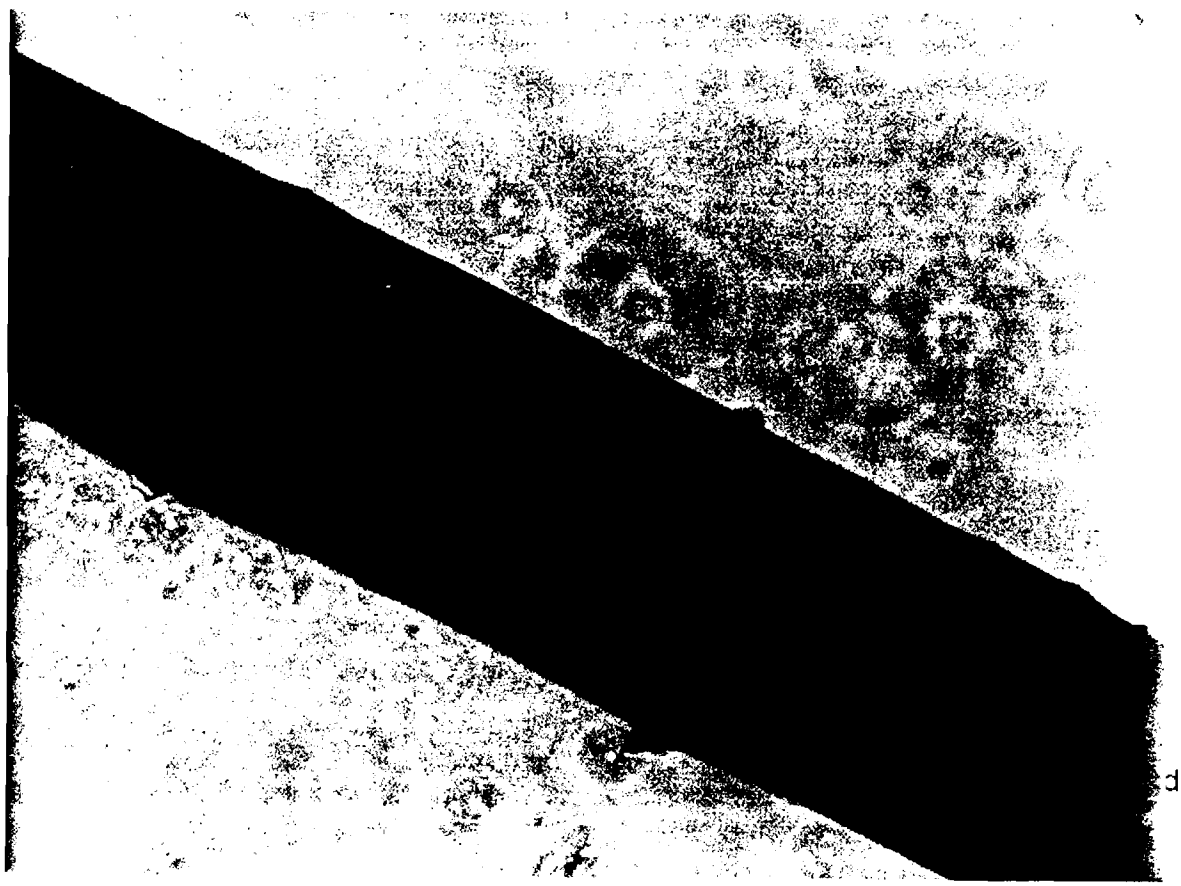
Figure 1B 7 Year Prolene Explants

dog 2007 site 6



dog 2019 site 2

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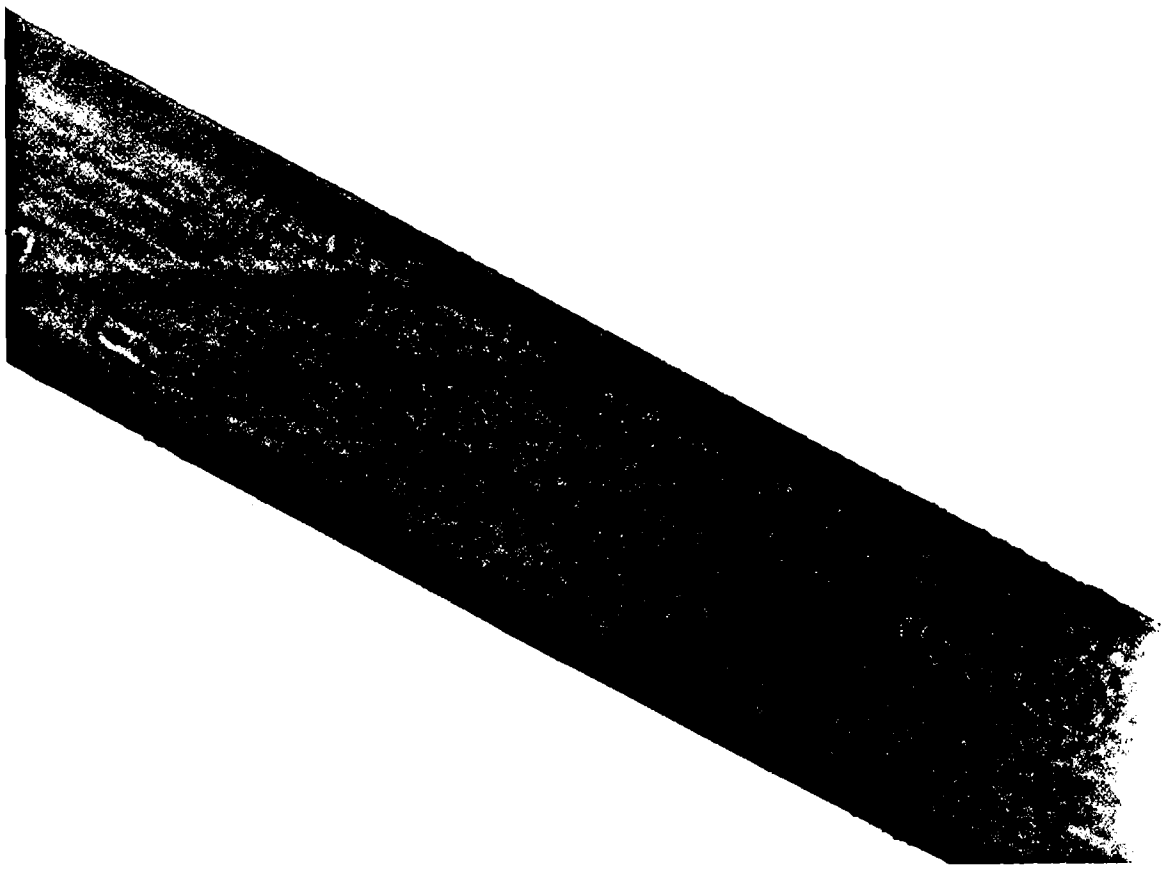
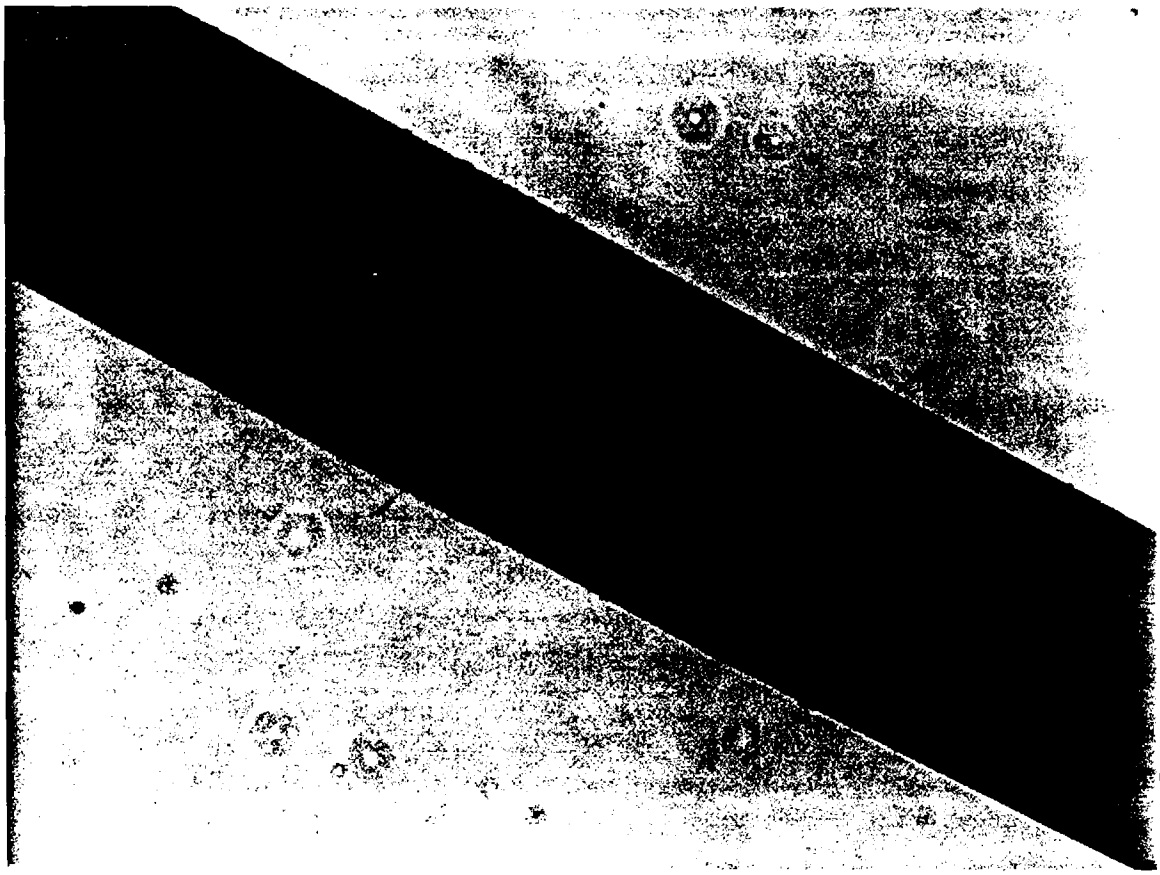
Figure 1C 7 Year Prolene Explants



dog 2007 site 1



dog 2019 site 3

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Figure 1D 7 Year Prolene Explants

dog 2001 site 4

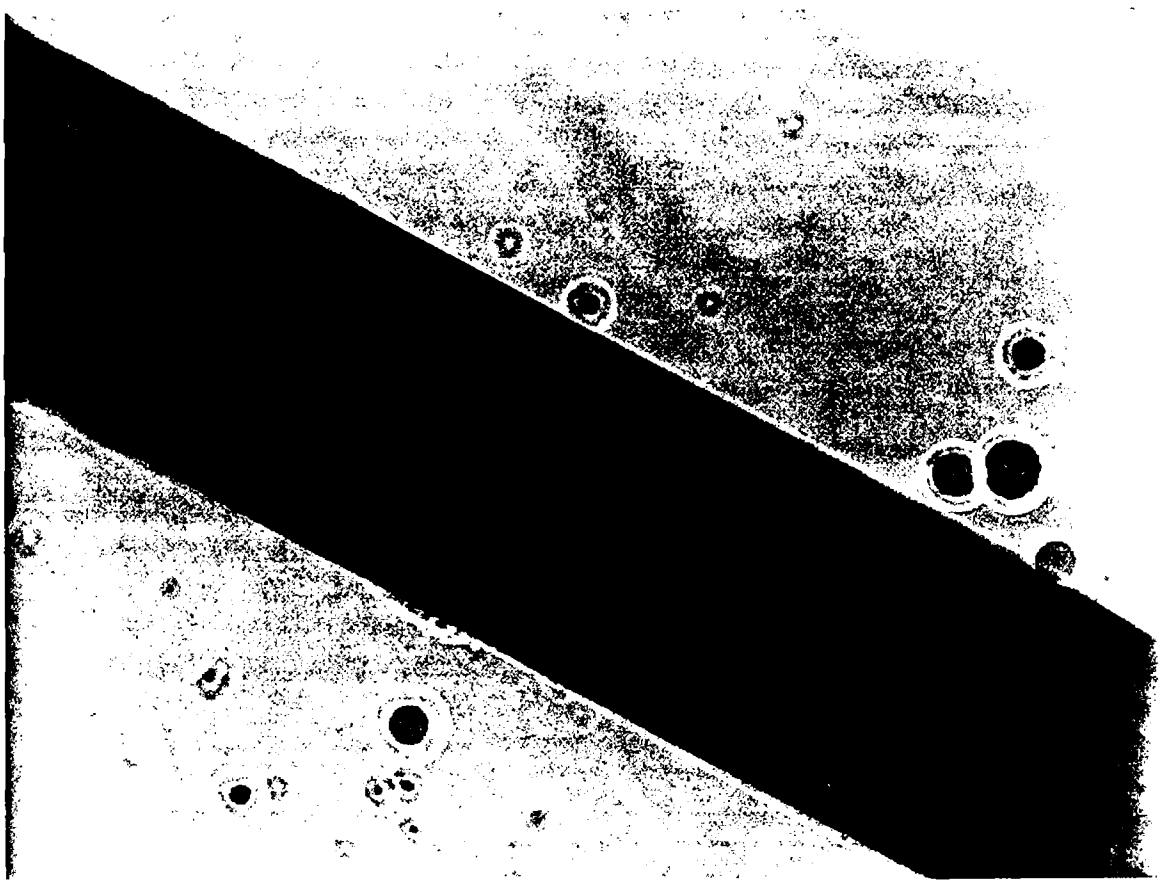

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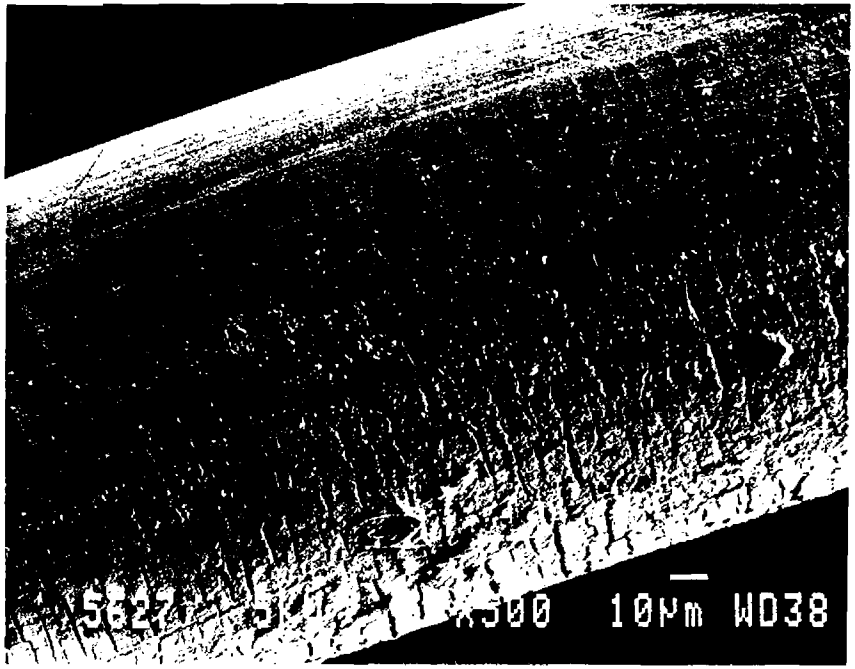
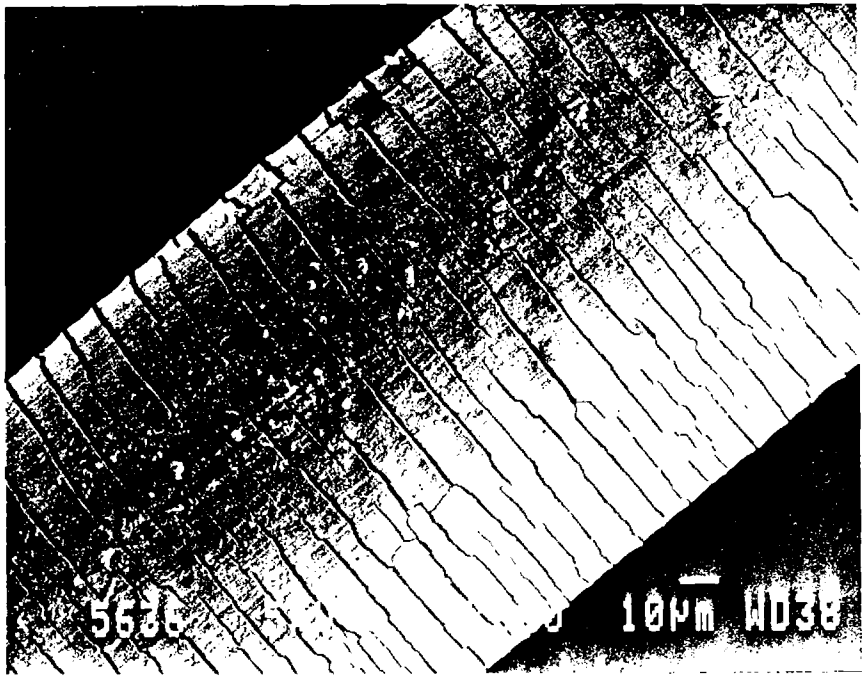
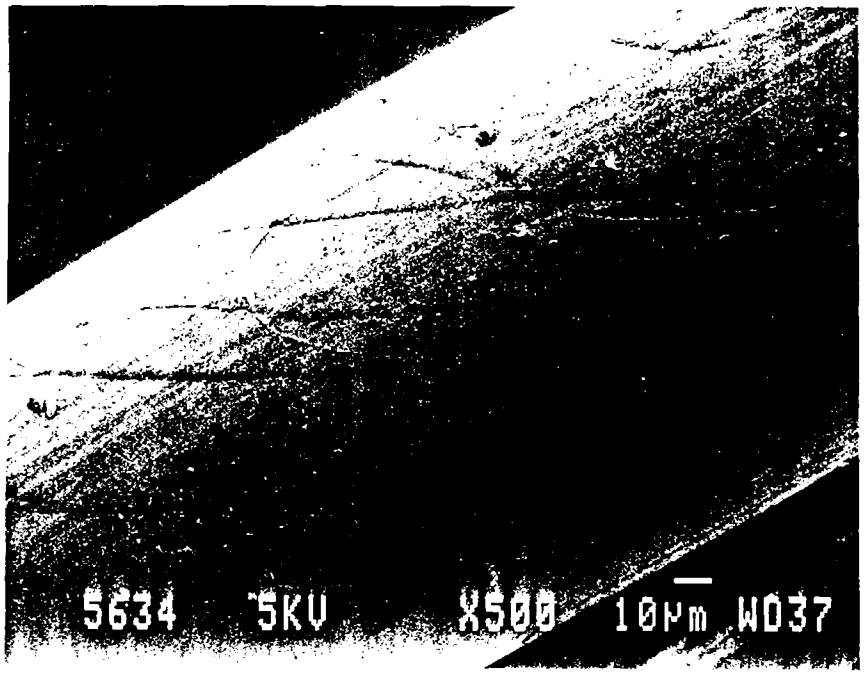
Figure 1 7 Year Prolene Explants

dog 2001 site 5




dog 2008 site 2




dog 2007 site 6

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Figure 2 7 Year Prolene Explants

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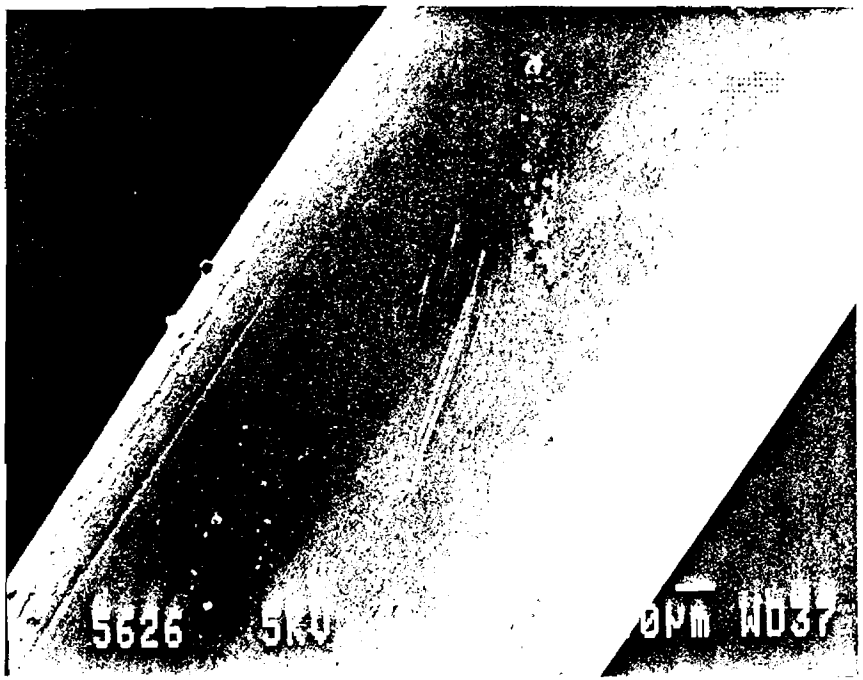
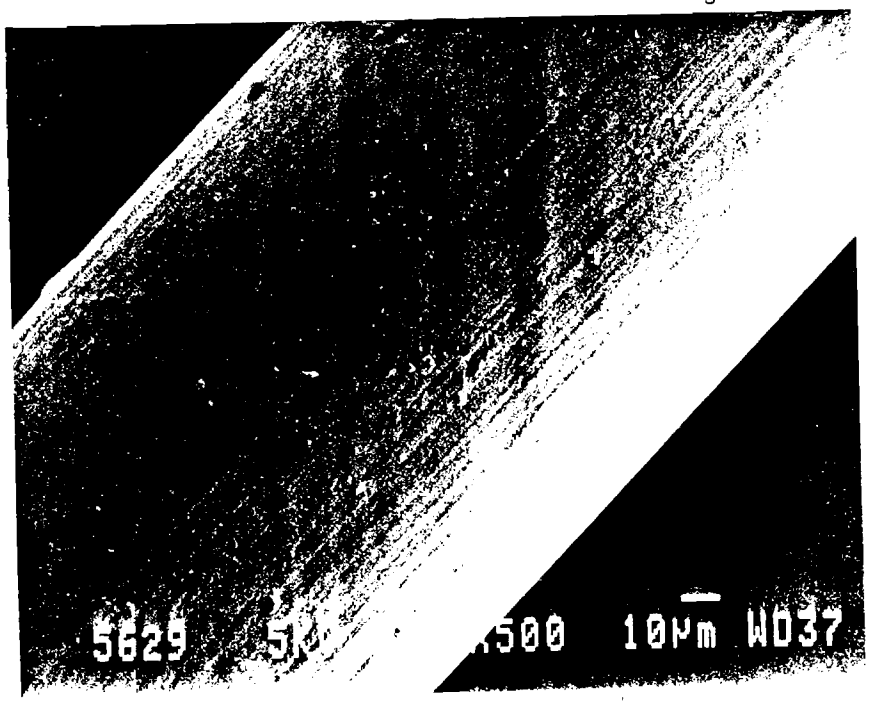
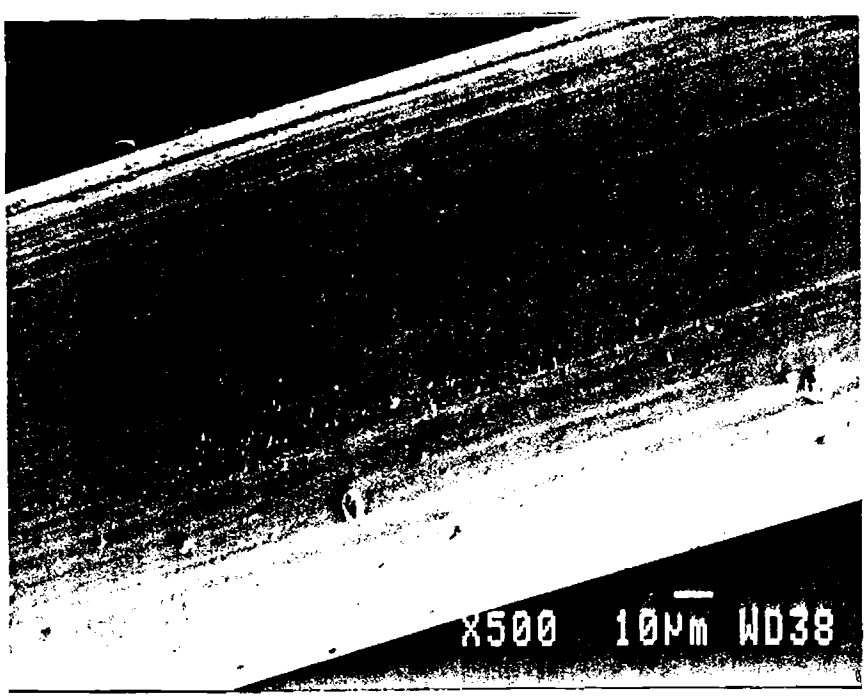
dog 2001 site 4

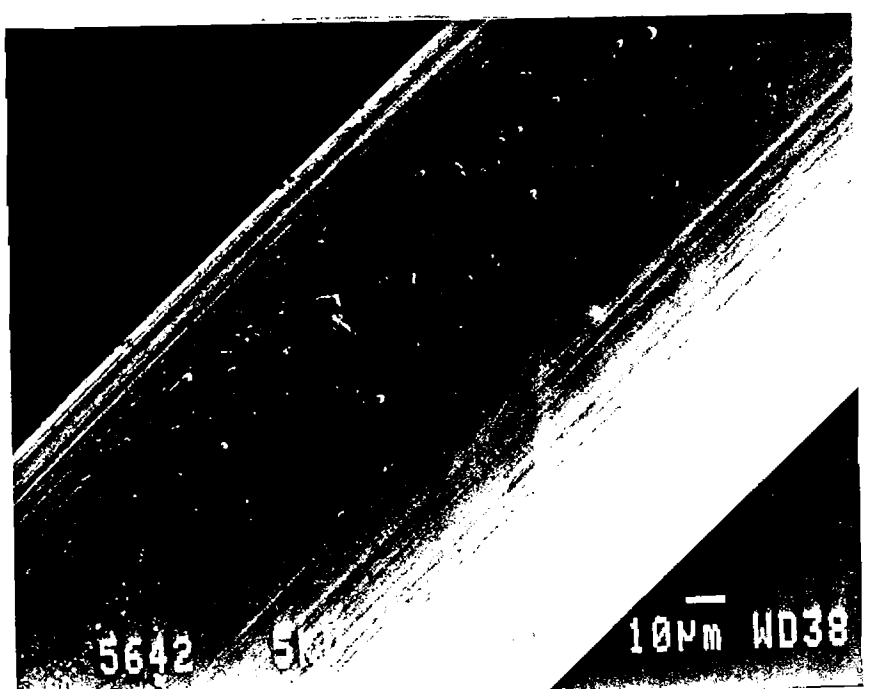



dog 2007 site 1



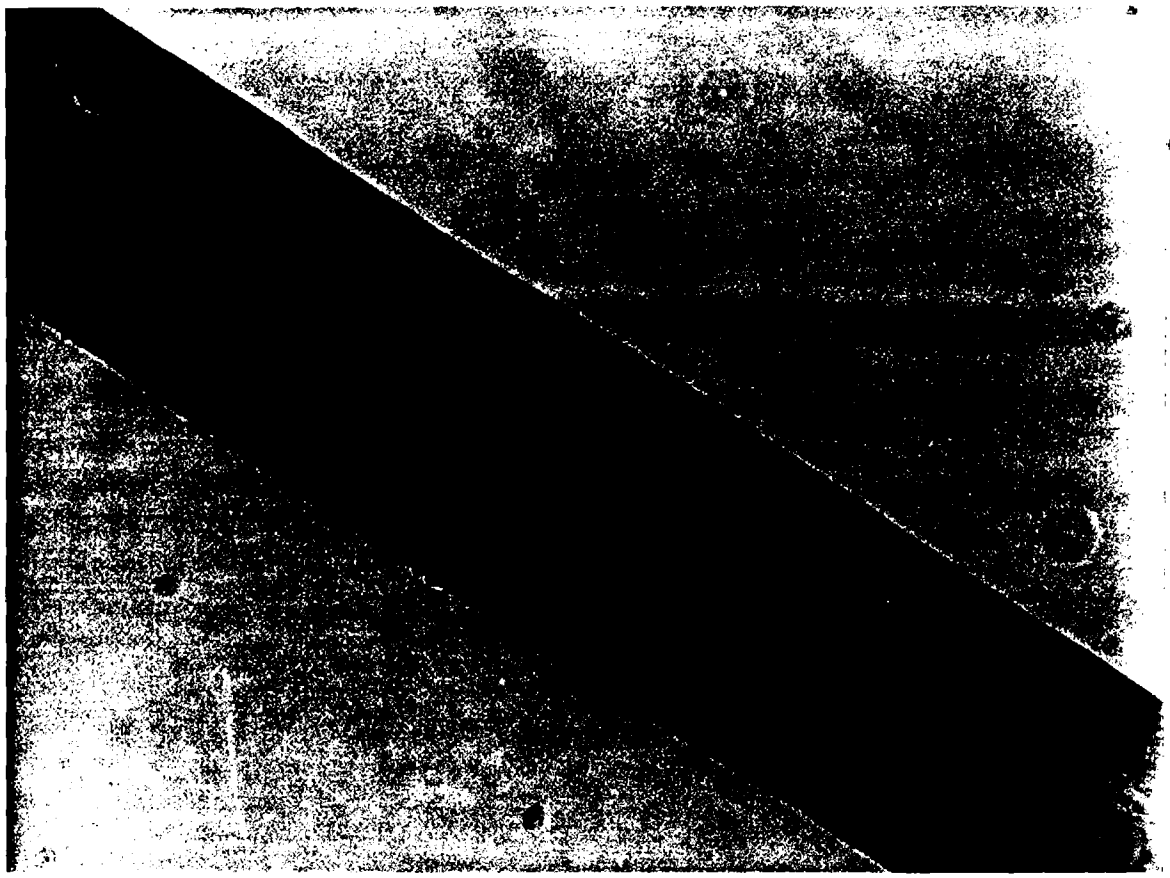




dog 2019 site 3




dog 2019 site 2

Figure 3A 7 Year Ethilon Explants



dog 2019 site 6

dog 2008 site 5

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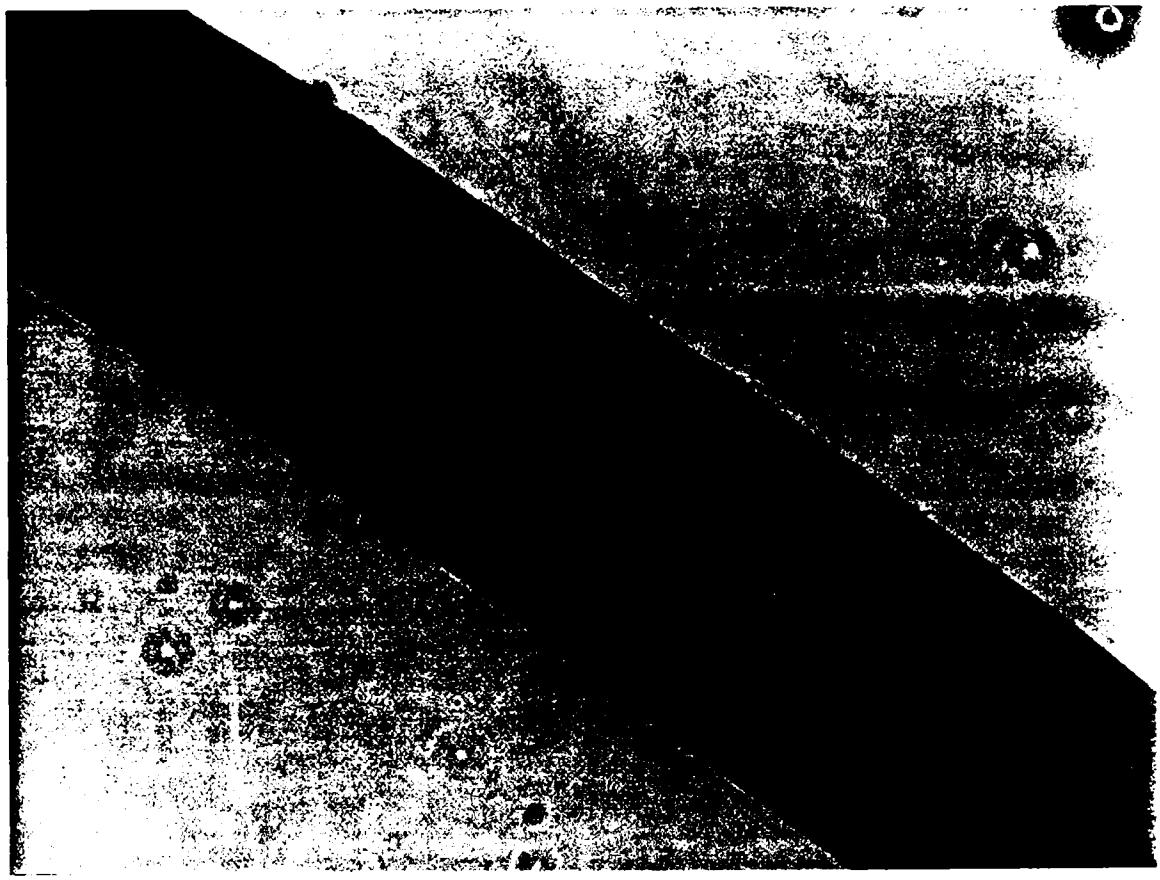
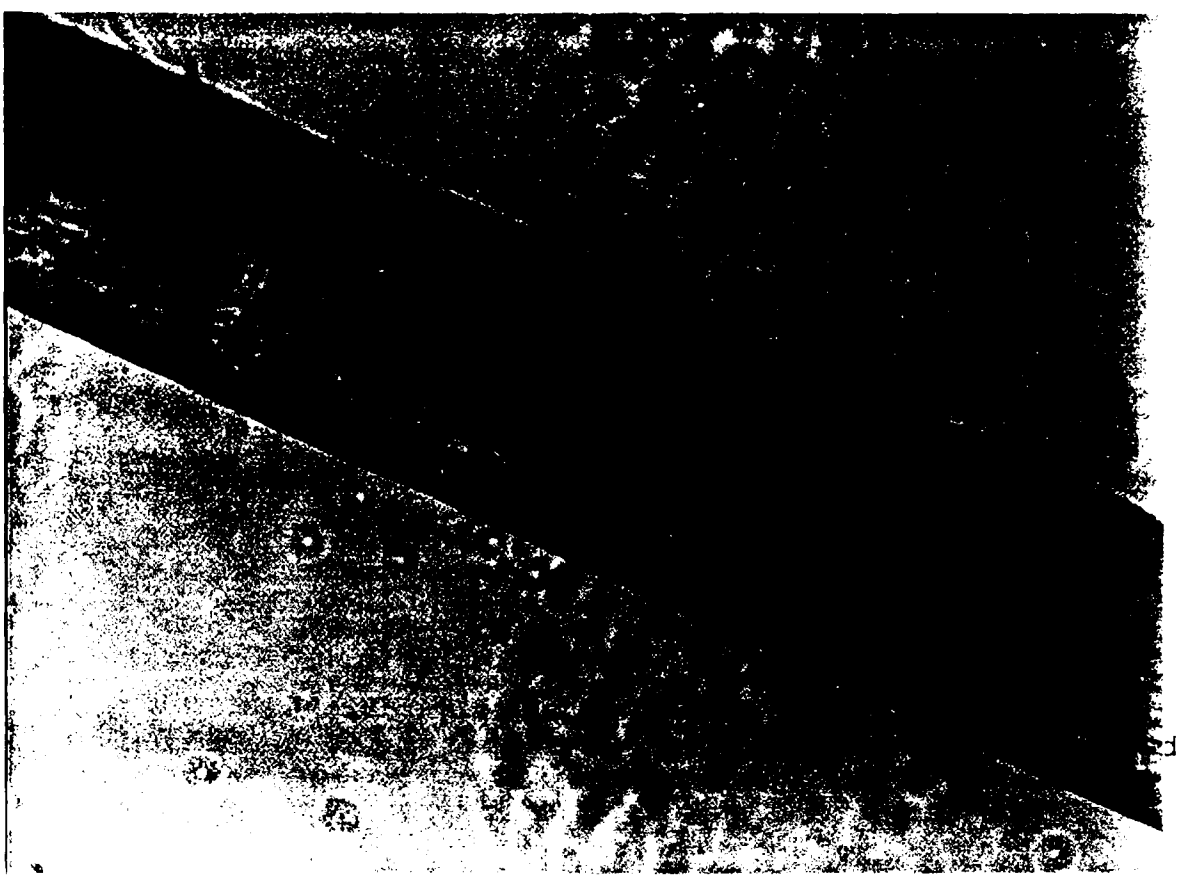
Figure 3B 7 Year Ethilon Explants



dog 2019 site 5



dog 2008 site 1

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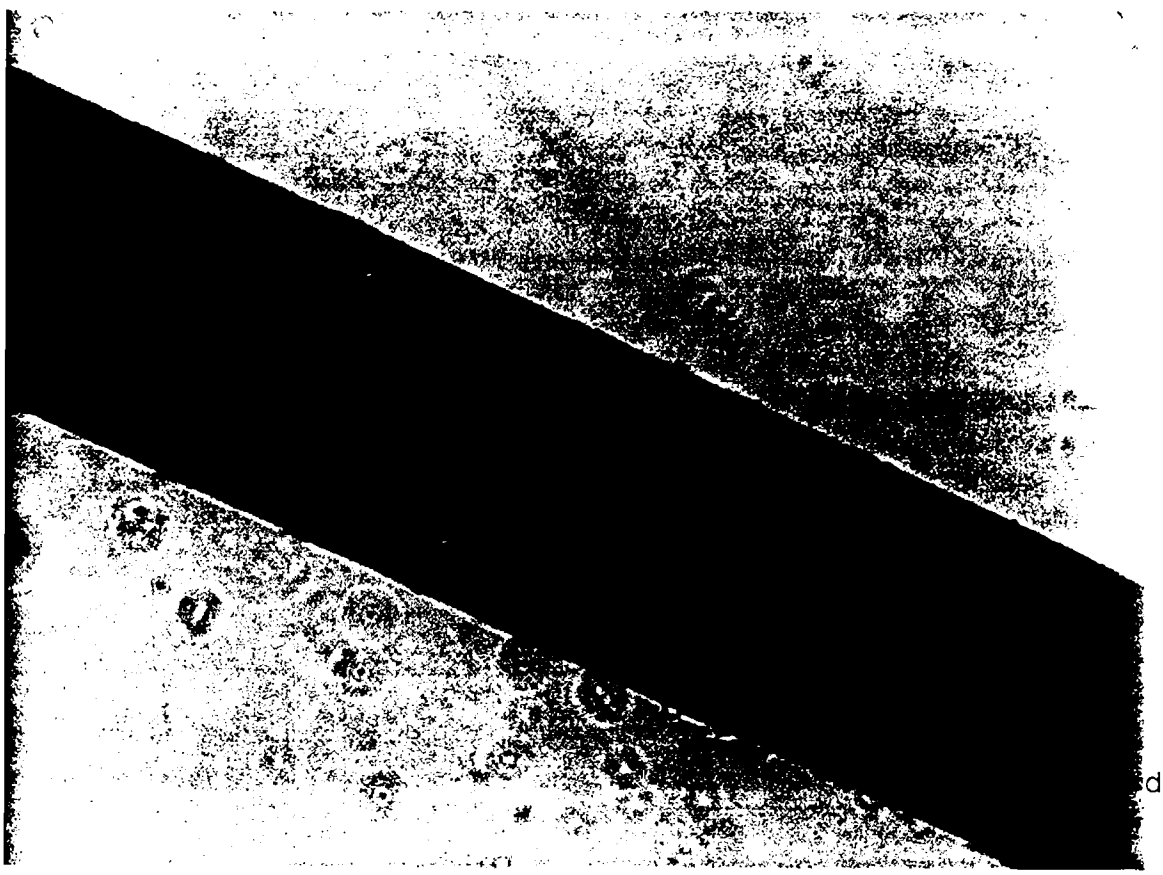
Figure 3C 7 Year Ethilon Explants

dog 2007 site 3



dog 2001 site 2

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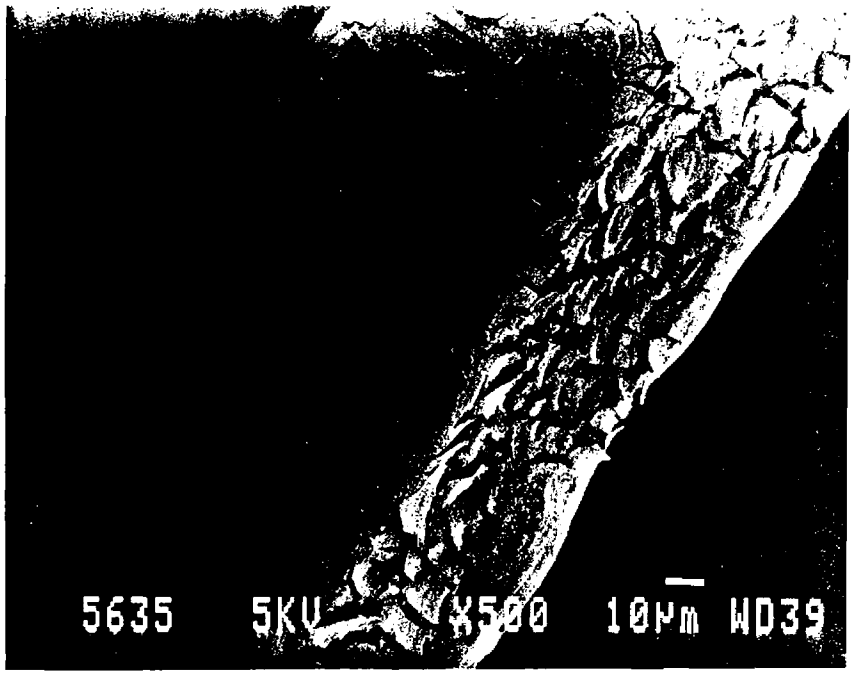
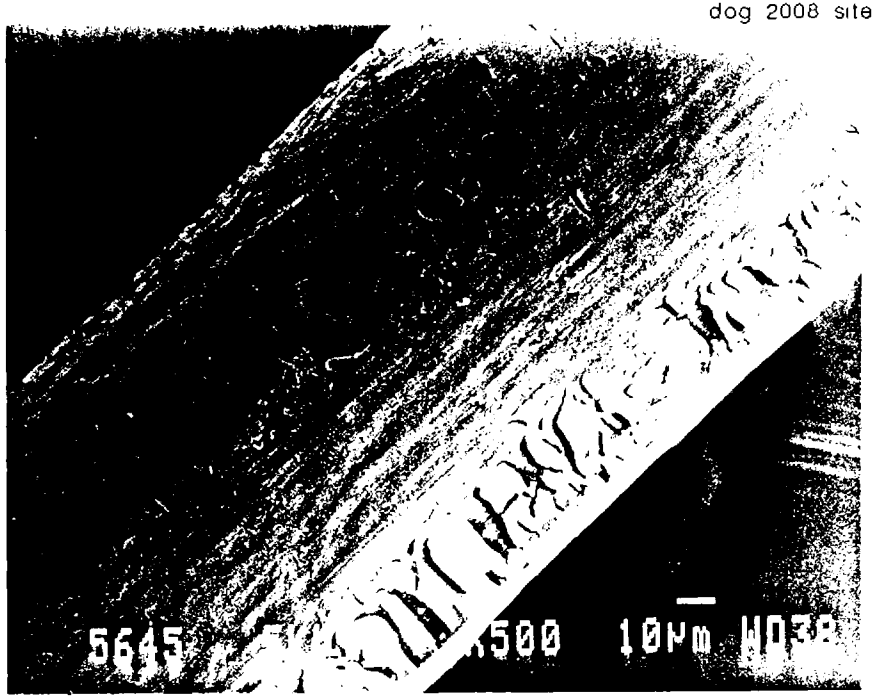
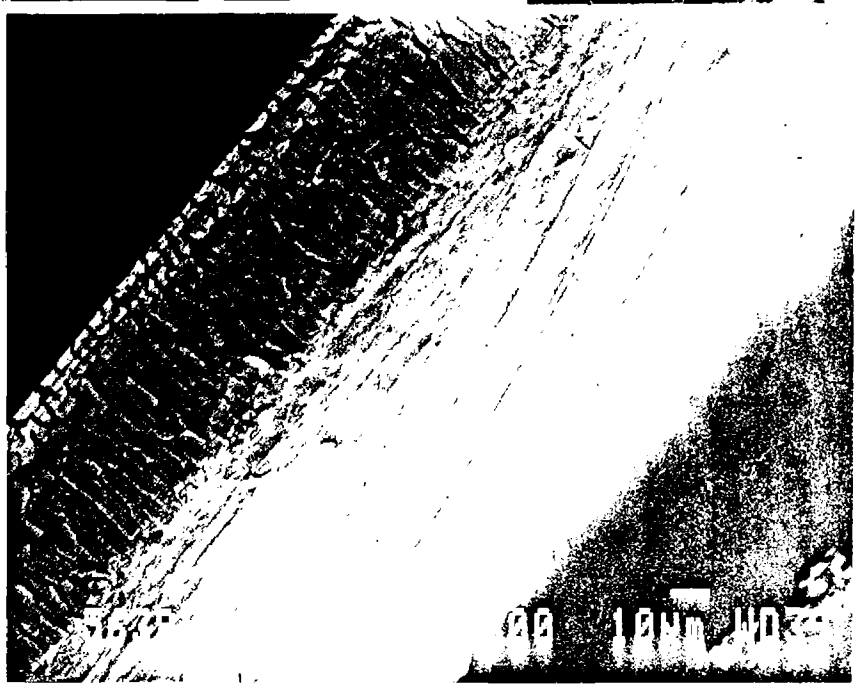
Figure 3 7 Year Ethilon Explants E. Lindemann 7/9/92 SR# 33985

dog 2008 site 1




dog 2008 site 5



dog 2019 site 5

Figure 4 7 Year Ethilon Explants

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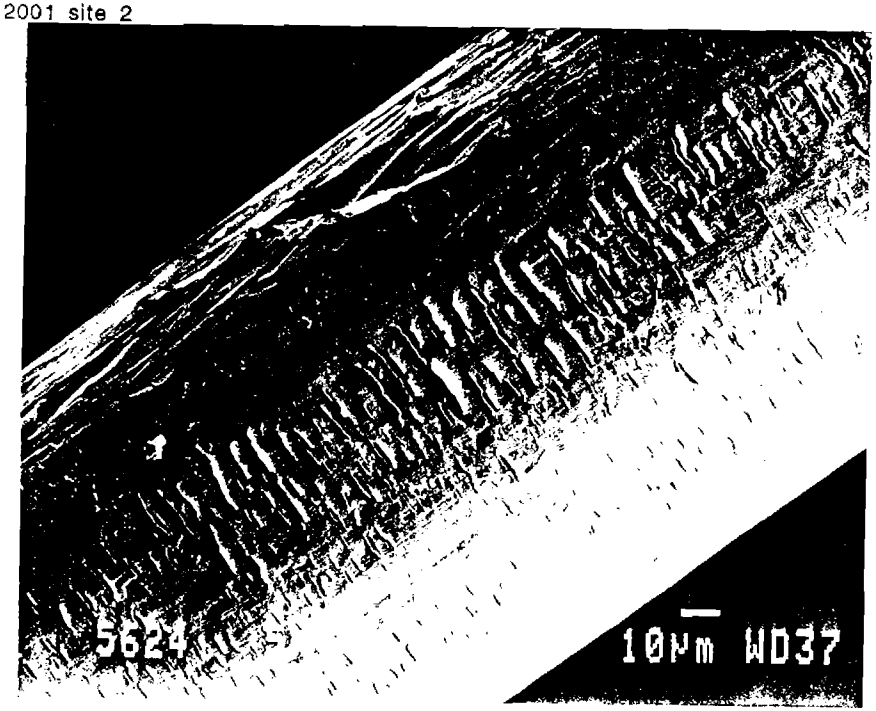
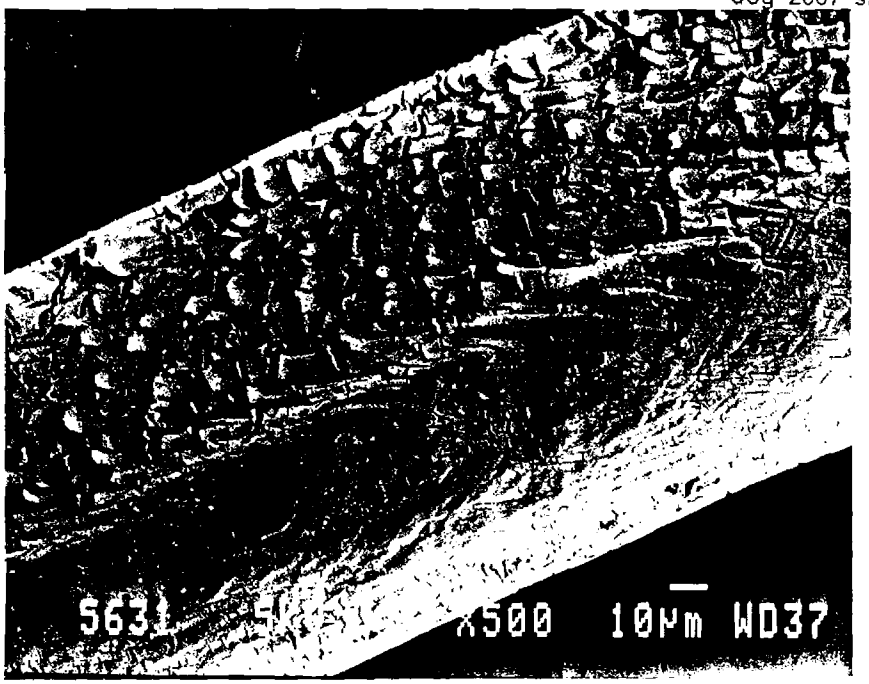
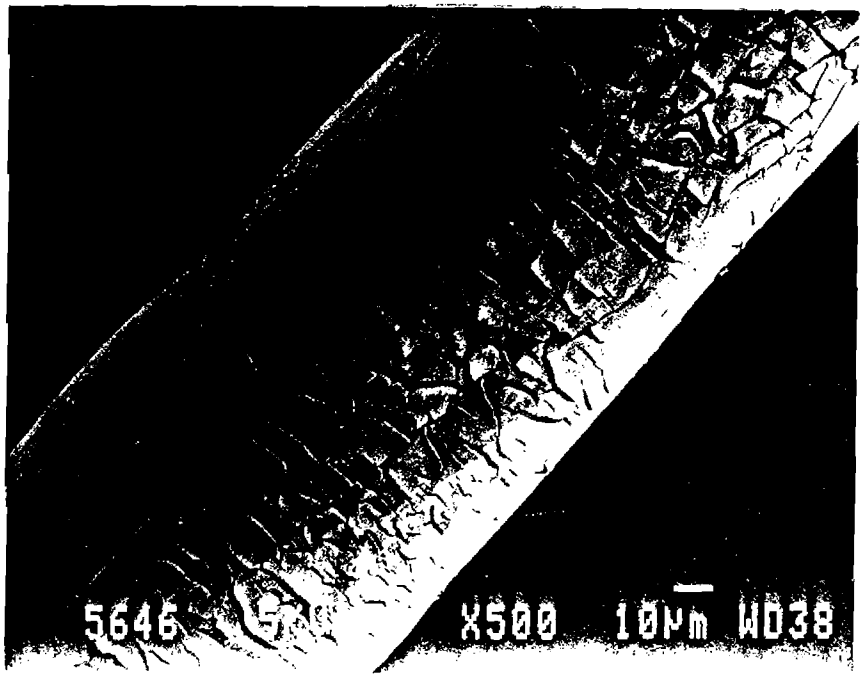
dog 2001 site 2



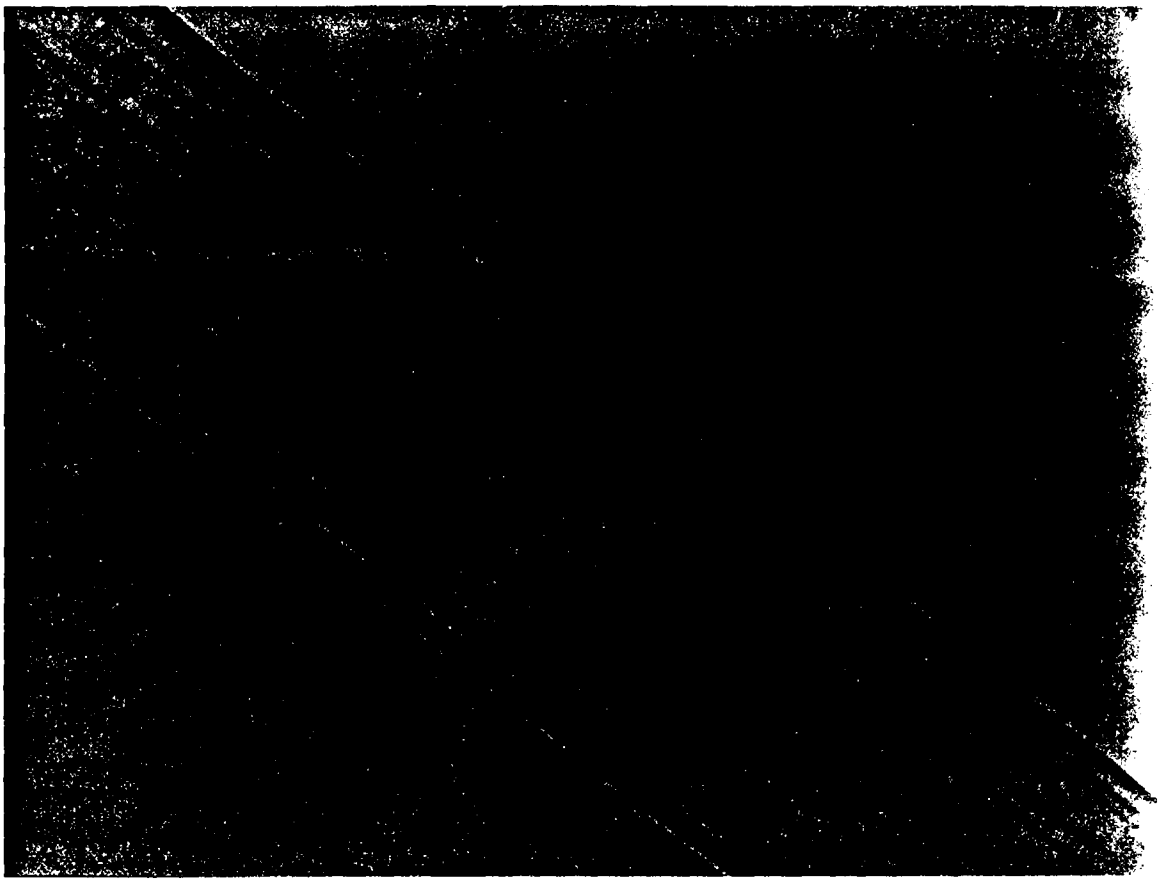

dog 2007 site 3



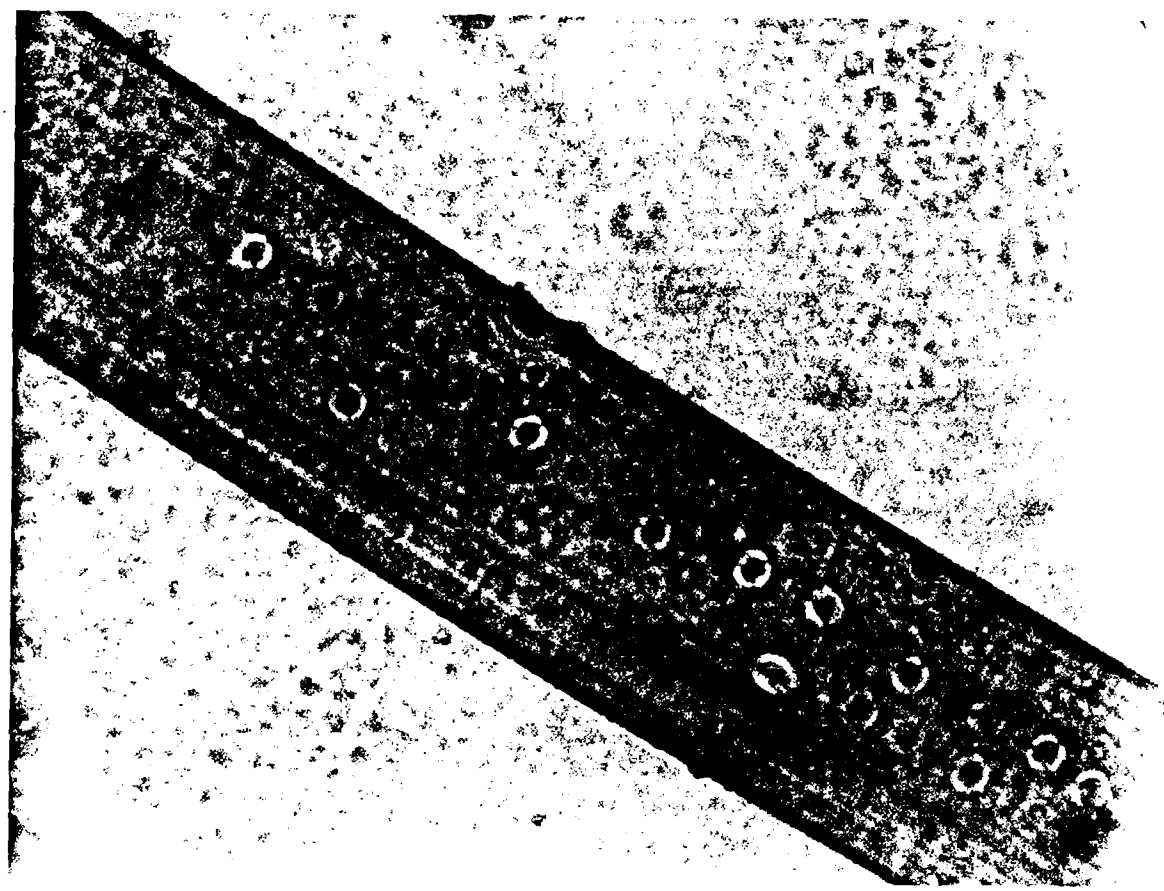




dog 2019 site 6

Figure 5A 7 Year PVDF Explants



dog 2007 site 4



dog 2001 site 1

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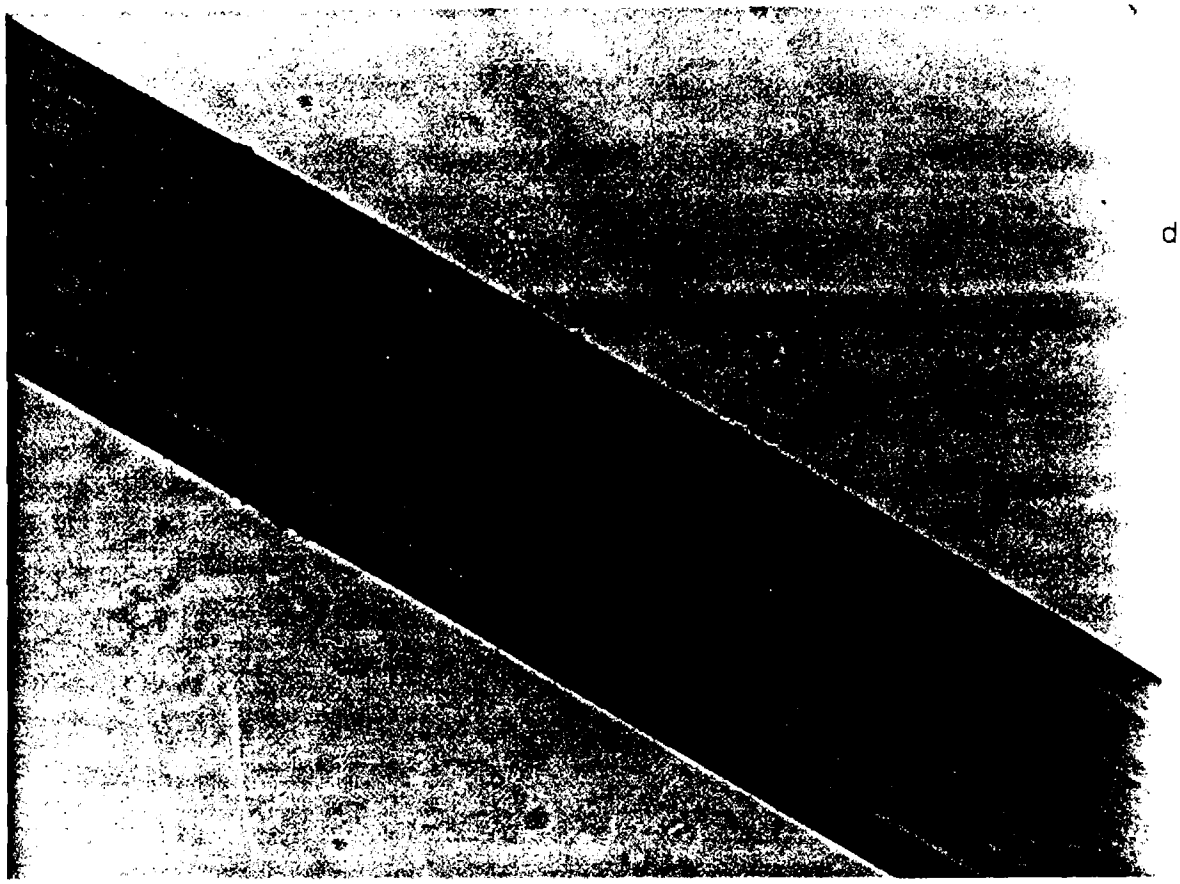
Figure 5B 7 Year PVDF Explants



dog 2008 site 4

dog 2007 site 5

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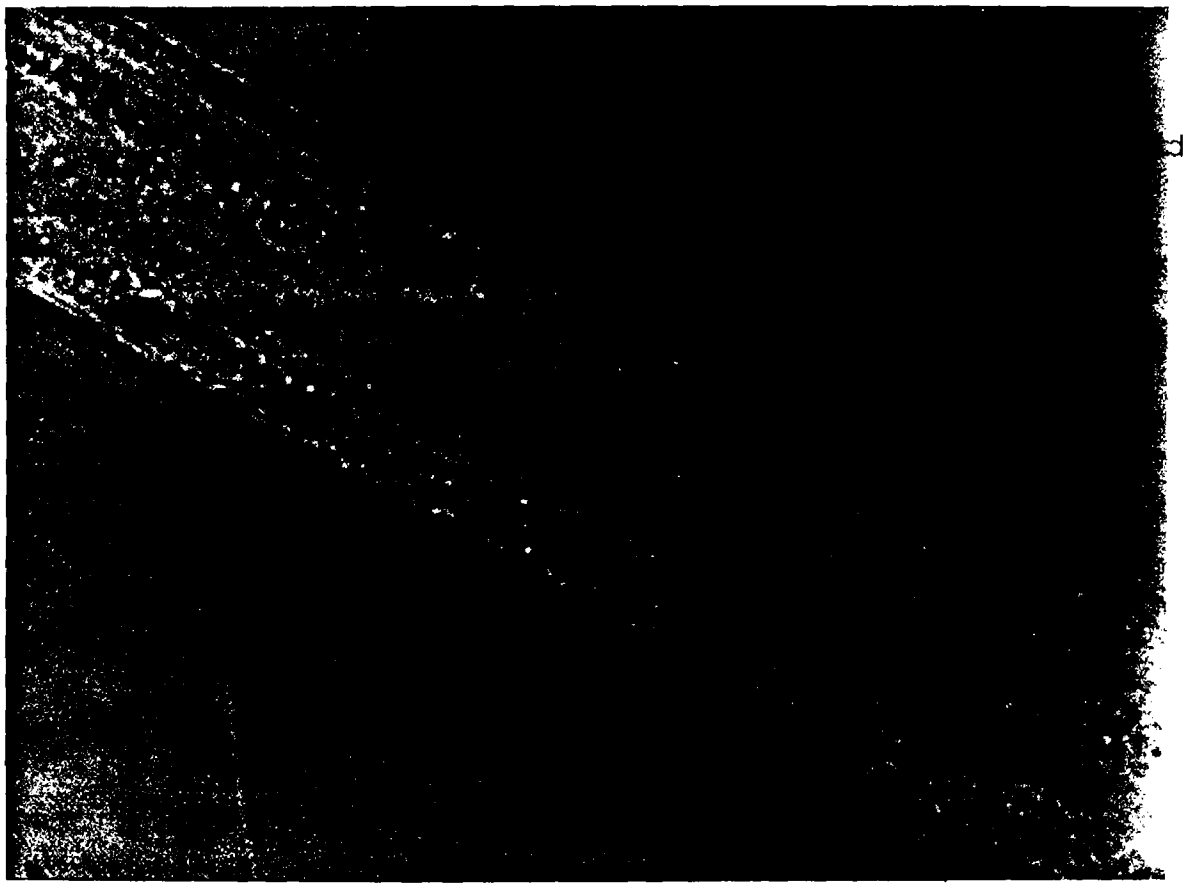
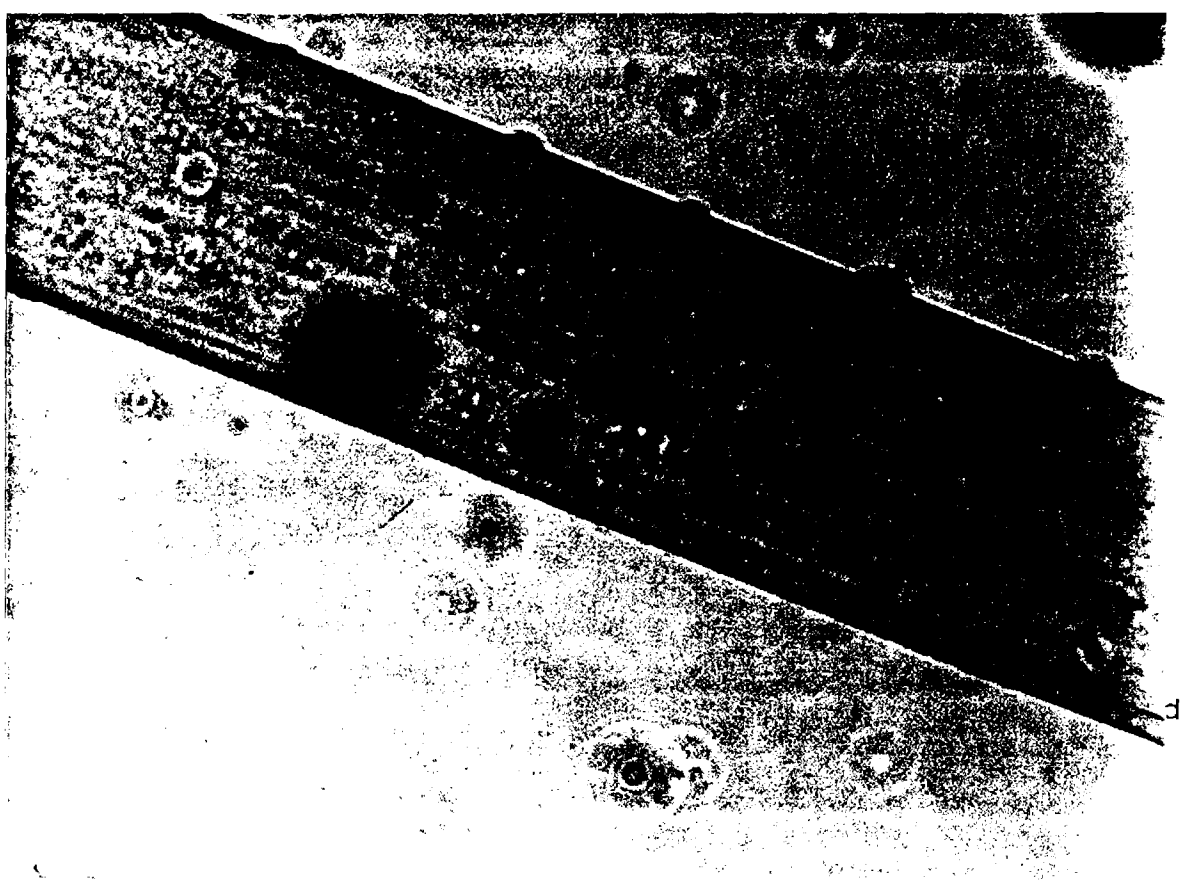
Figure 5C 7 Year PVDF Explants



dog 2008 site 6



dog 2019 site 4

E. Lindemann 7/15/92 SR# 33985

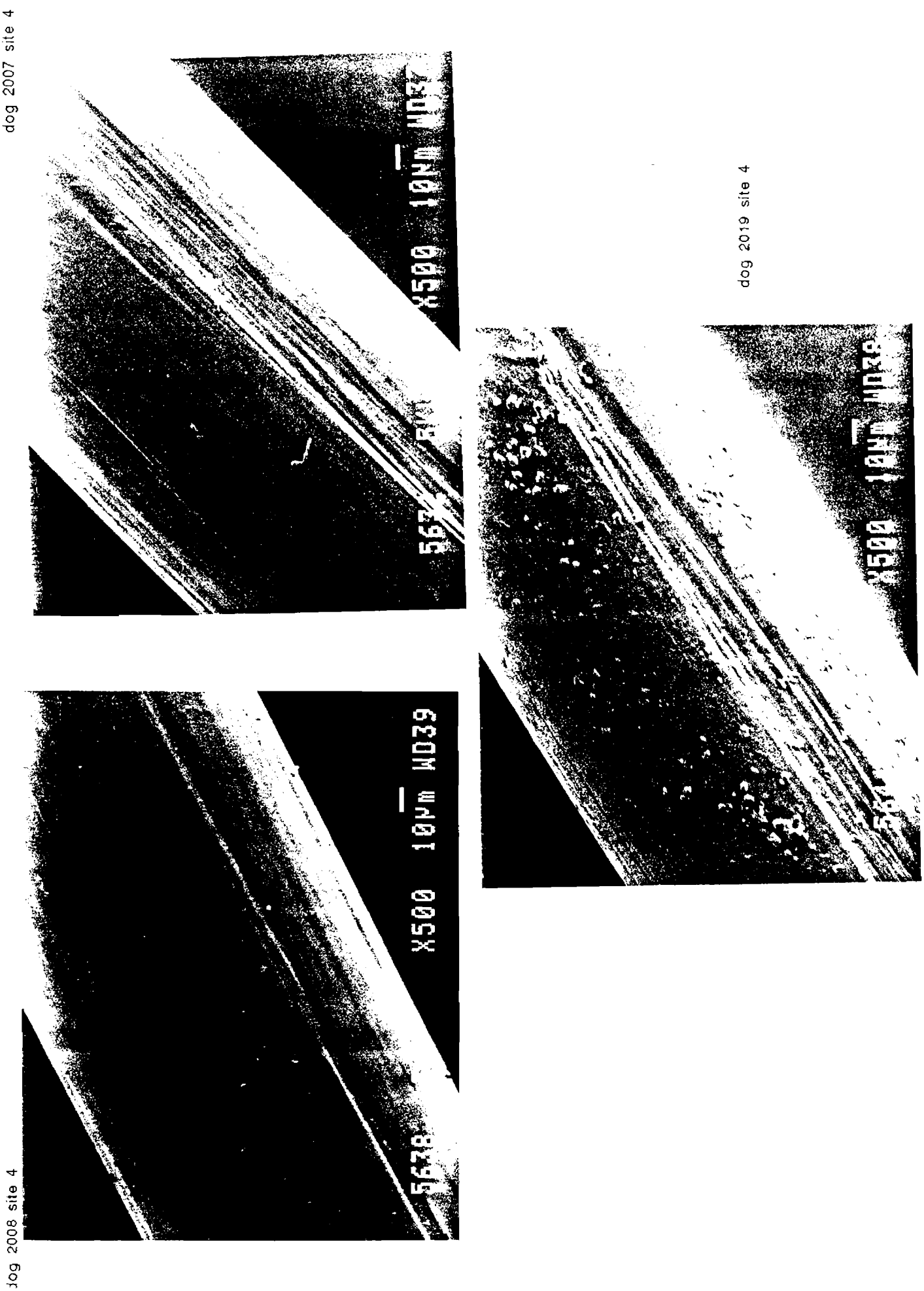
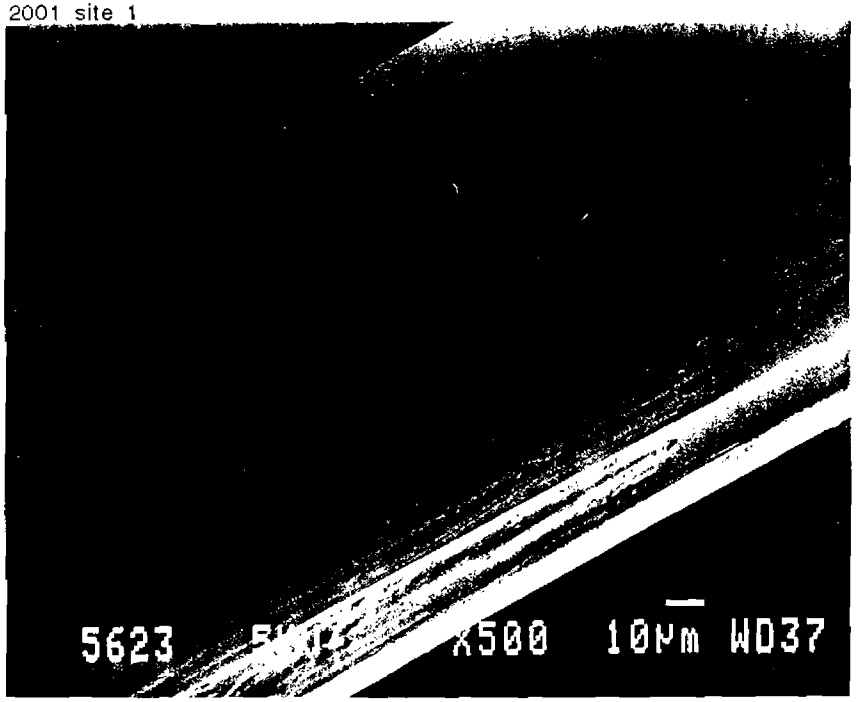



Figure 5 7 Year PVDF Explants

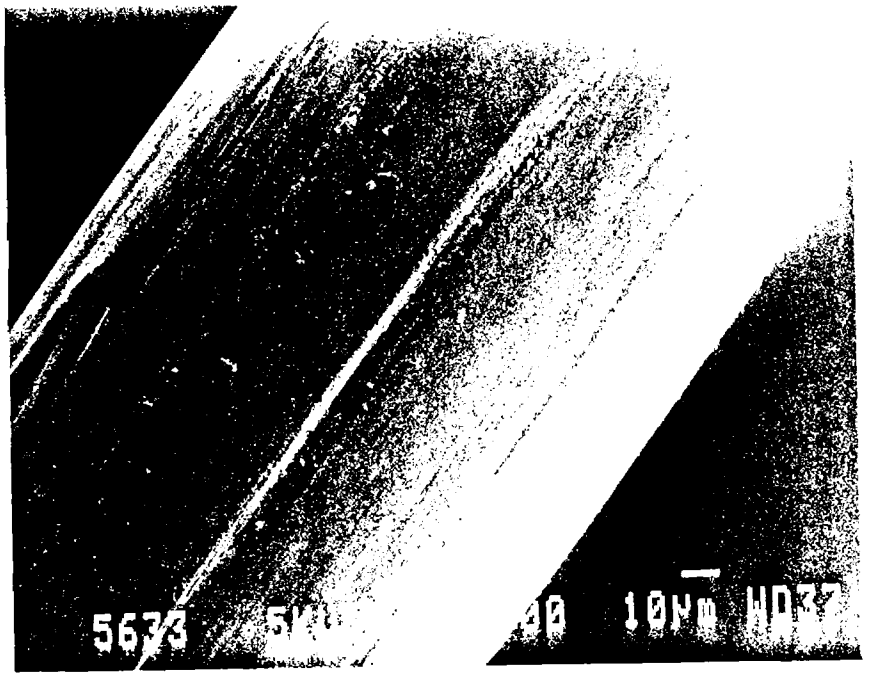
Figure 6 7 Year PVDF Explants

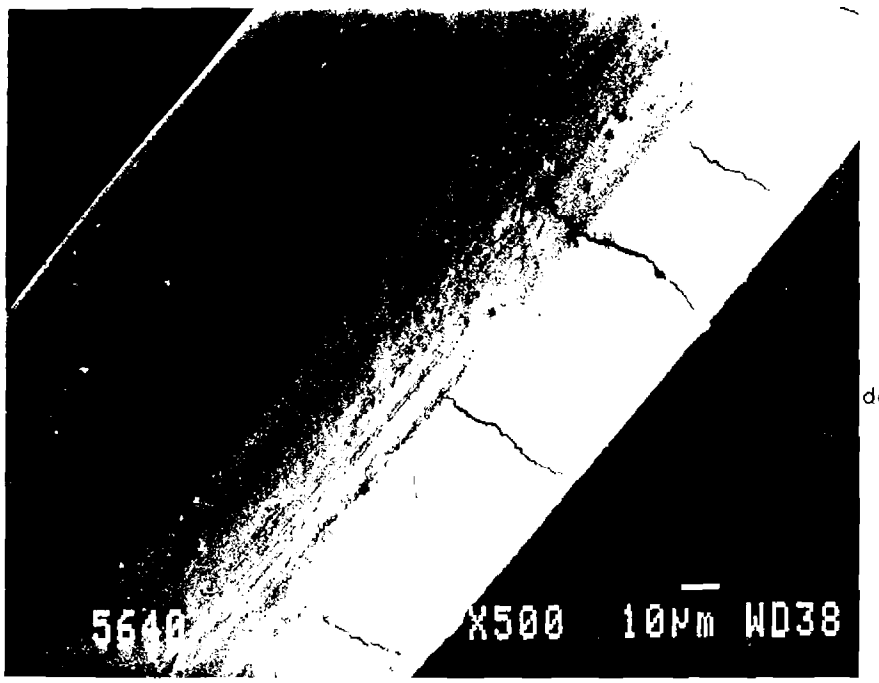
E. Lindemann 7/9/92 SR# 33985

dog 2001 site 1



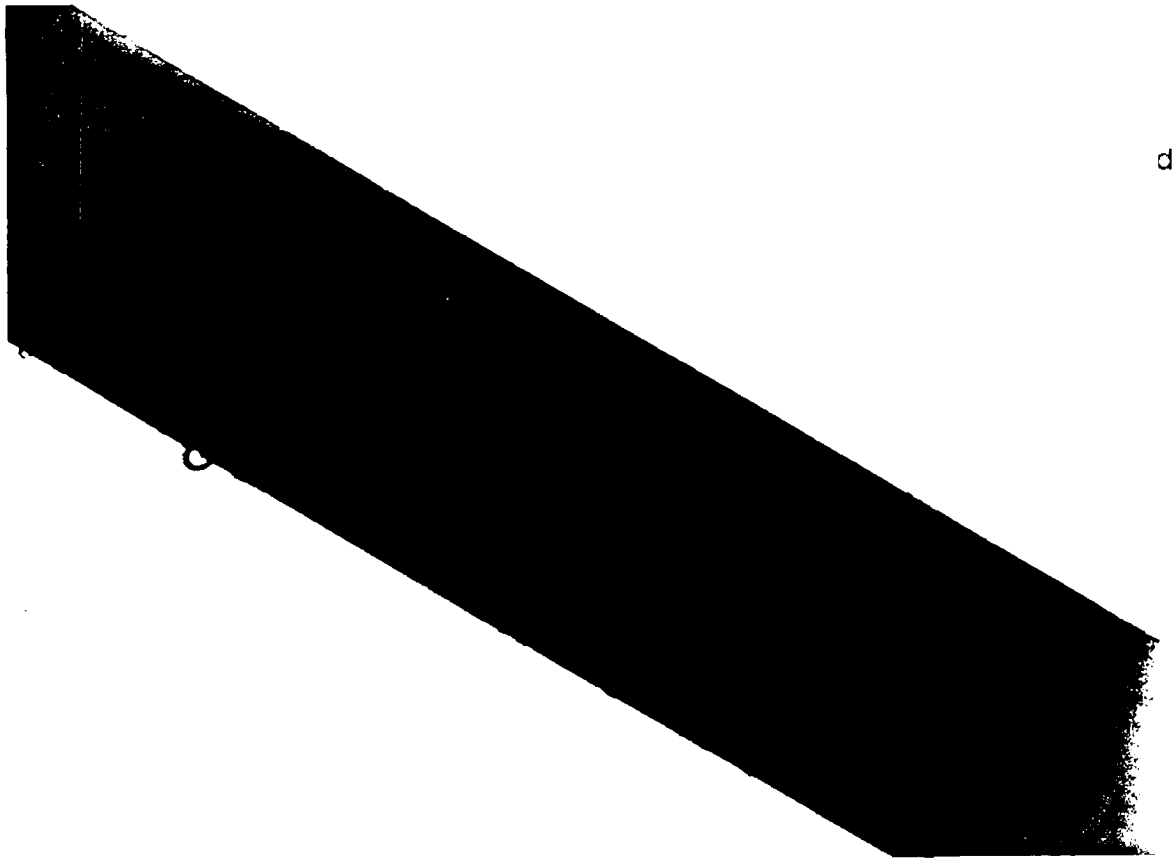

dog 2007 site 5



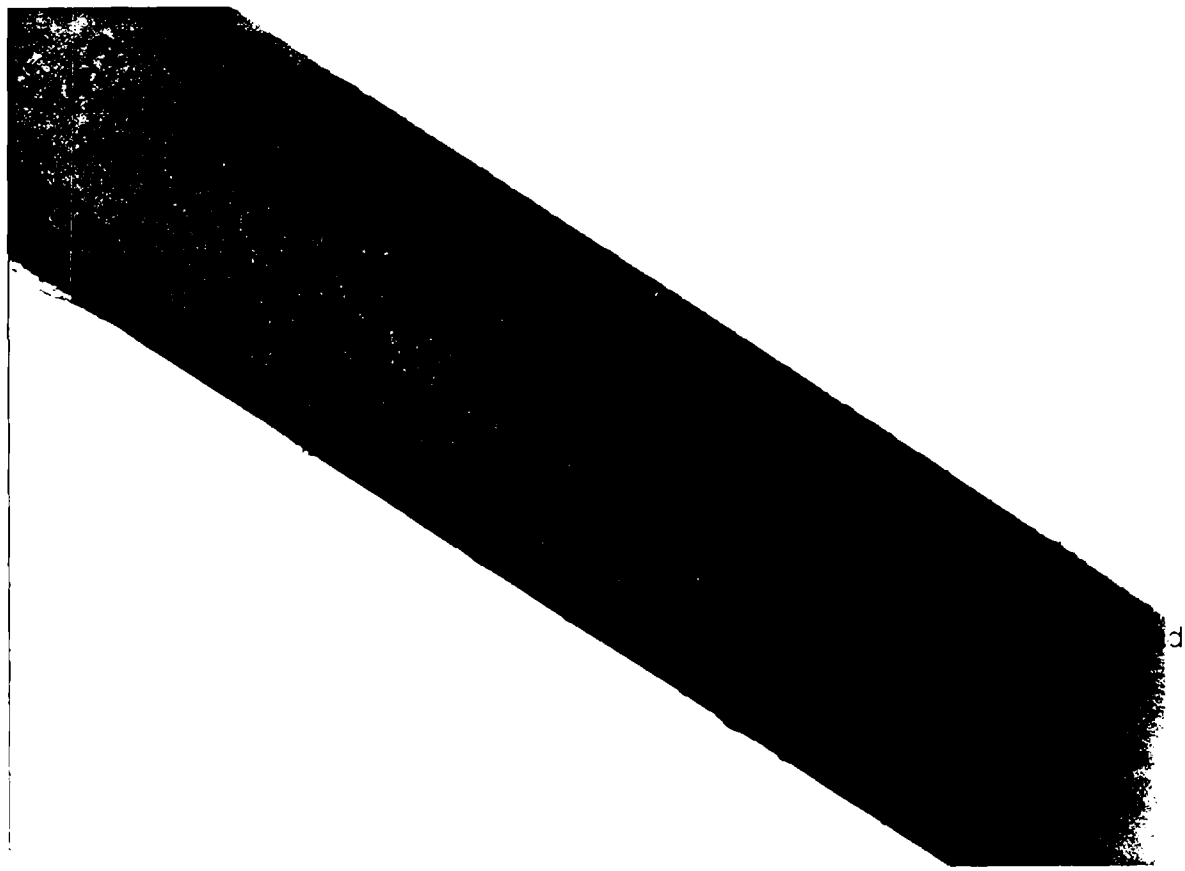




dog 2008 site 6

Figure 7A 7 Year Novafil Explants



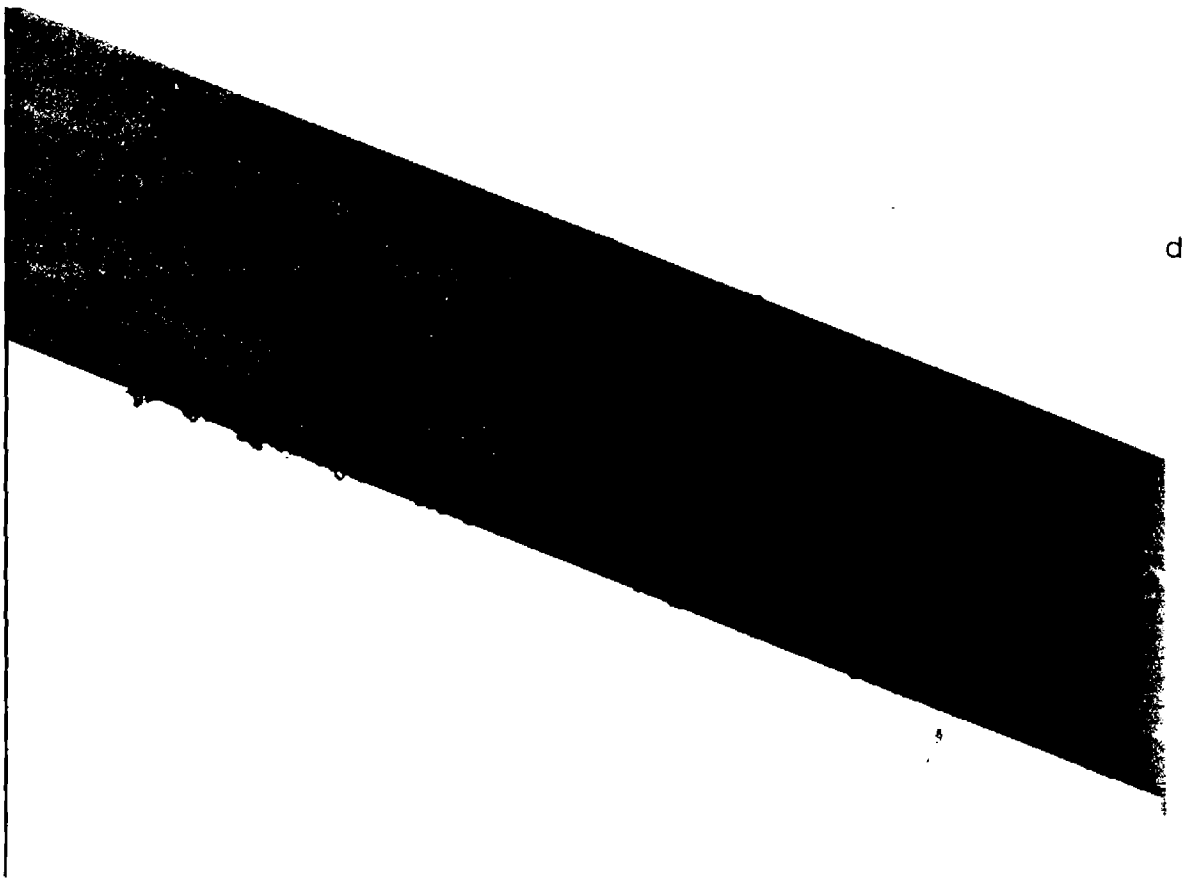
dog 2001 site 6



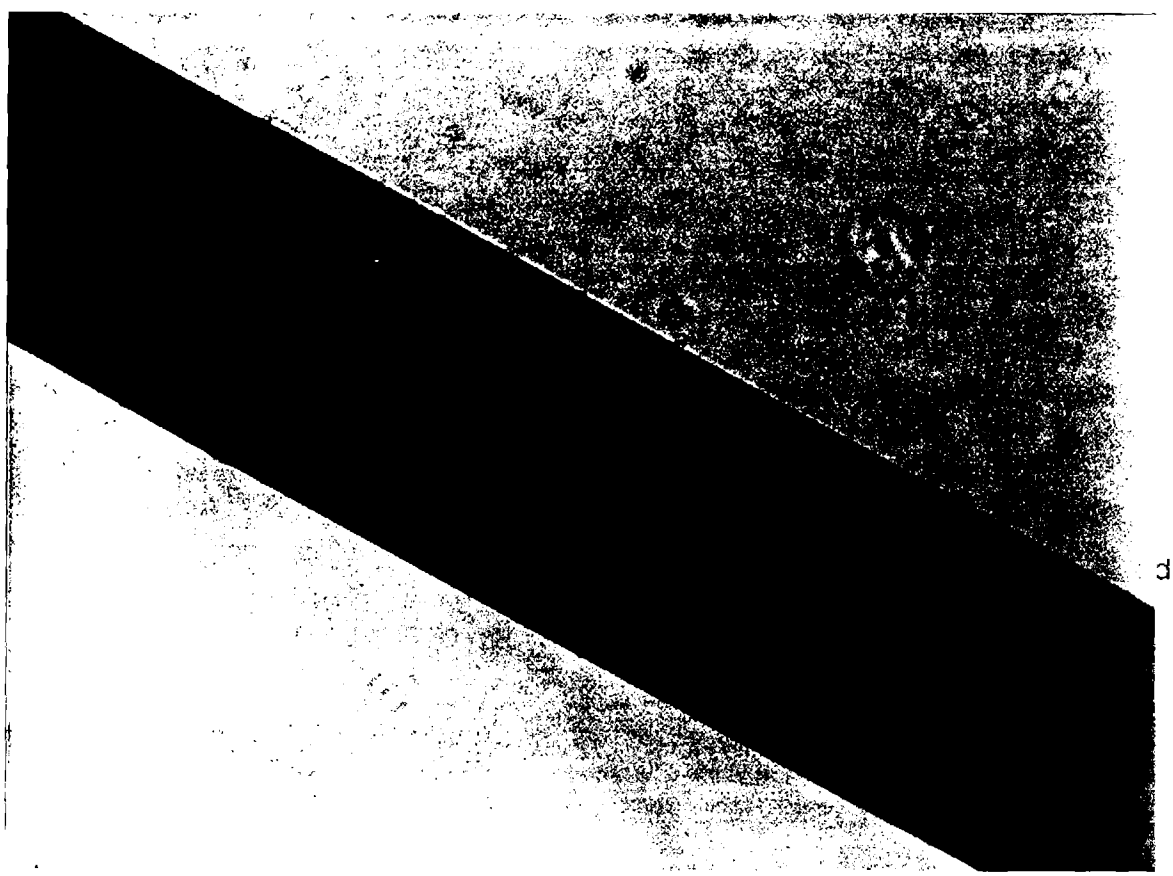
dog 2001 site 3

E. Lindemann 7/15/92 SR# 33985

Figure 7B 7 Year Novafil Explants



dog 2007 site 2



dog 2019 site 1

E. Lindemann 7/15/92 SR# 33985

Figure 7C 7 Year Novafil Explants

dog 2008 site 3

Lindemann 7/15/92 SR# 33985

E. Lindemann 7/9/92 SR# 33985

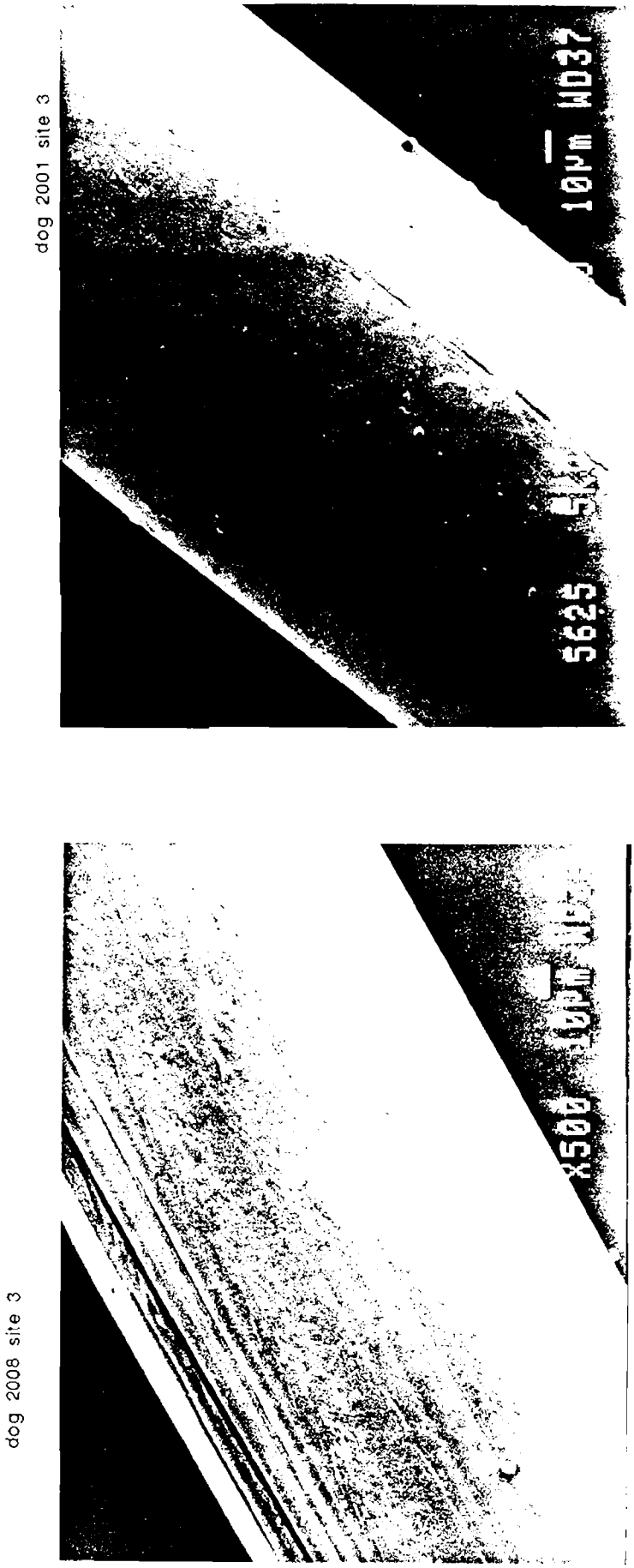
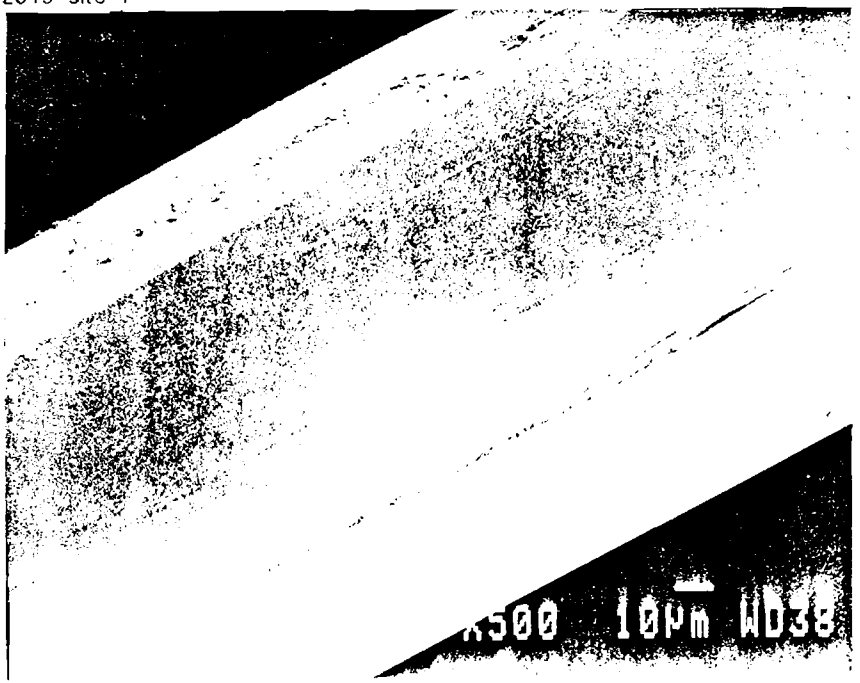



Figure 7 7 Year Novafil Explants

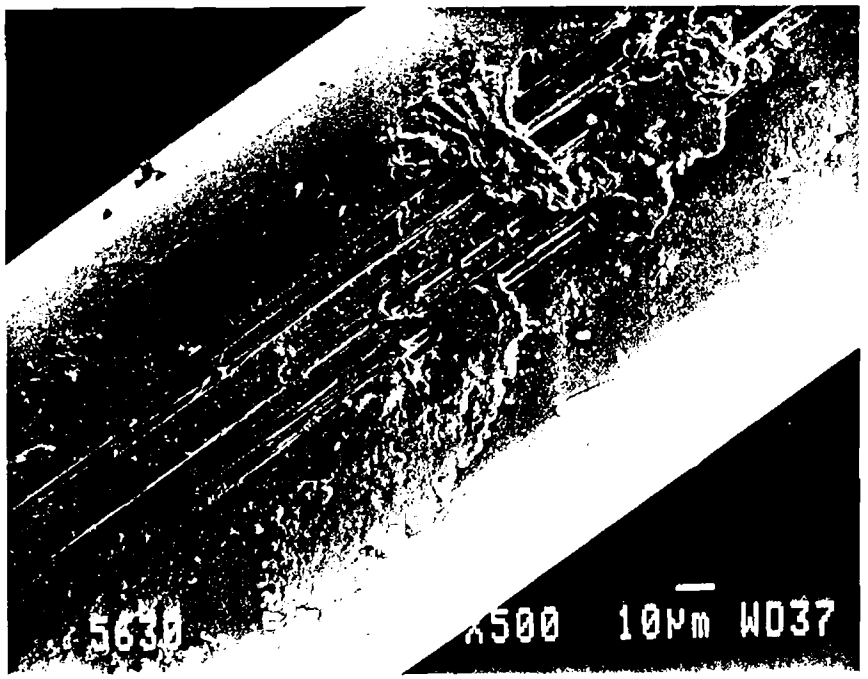
Figure 8 7 Year Novafil Explants

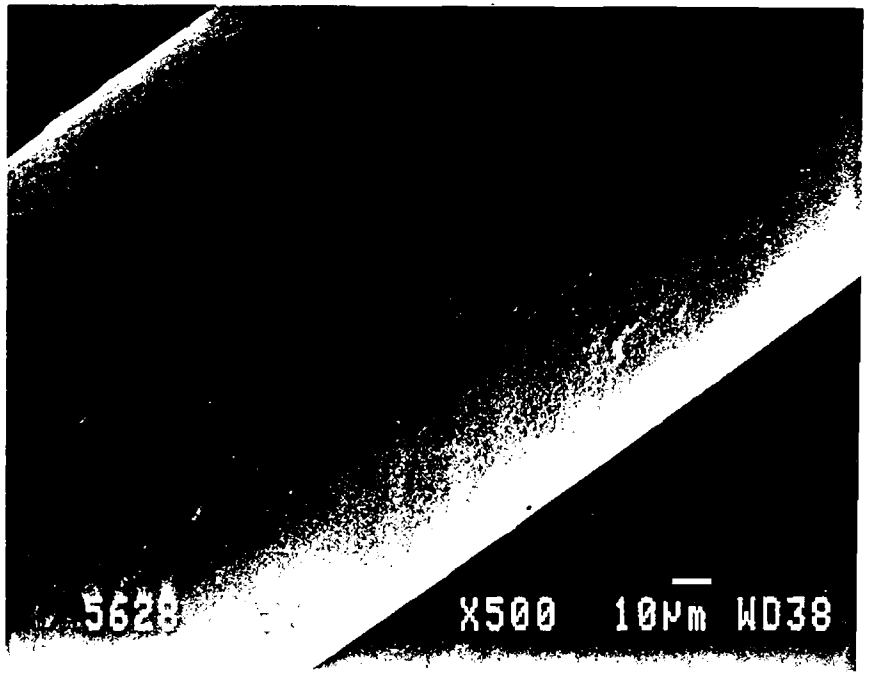
E. Lindemann 7/9/92 SR# 33985

dog 2019 site 1




dog 2007 site 2




dog 2001 site 6

SAMPLE CONTROL #: J 3028

# ETHICON, INC.

## ANALYTICAL CHEMISTRY DEPARTMENT

SERVICE REQUEST #: ~~34002~~ 34003

| REQUESTOR | DEPARTMENT | EXT. | DATE SUBMITTED | PROJECT NO. | REQUESTOR'S MANAGER AUTHORIZATION |
|---|---|---|---|---|---|
| V. AGARWAL | 64523 | X2205 | June 23'92 | 16102 | B. Matlaga |

SIZE 5-0, DOG #2007 **7 YEAR EXPLANT

SAMPLE IDENTIFICATION, SPECIAL STORAGE CONDITIONS, PRECAUTIONS

1. NOVAFIL SITE 2
2. ETHILON SITE 3
3. PVDF (Undyed) Site 4
4. PVDF (Undyed) Site 5
5. PROLENE Site 6
6. PROLENE Site 1

} 7 Year Explants for [10 Year Prolene BSR Study]

ANALYSIS REQUESTED/PURPOSE:

| | | | | | |
|---|---|---|---|---|---|
| (IR) | GC | (GPC) | DSC | (OM) | % ; PPM |
| NMR | TLC | (IV) | TGA | (HSM) | 0, H,O ETO |
| MS | LC | XRD | TMA | (SEM) | DYE MONO |
| U/V | WET | DEN | DMA | EDXA | CRYST COMP |

OTHER: FOR OM + SEM DATA SEE SR 34070

SAMPLE DISPOSITION

| | SENT TO | SUPERVISOR/ANALYST |
|---|---|---|
| 6 ATTACHED | | |
| 0 CONTACT REQ. | | |
| 0 RETURN | | |

NO. SAMPLES

TEST REPORT: Samples of each explant were prepared as hot-pressed films by HSM and examined by FT-IR.

SITE 1 - PROLENE : IR spectrum obtained corresponds to polypropylene
SITE 2 - NOVAFIL : " " " " Novafil (poly(butylene Terephth- -poly butoxy ether
SITE 3 - ETHICON " " " " Nylon 6 (ETHICON)
SITE 4 - PVDF : " " " " polyvinylidene fluoride
~~SITE 5 - PROLENE~~ ~~" " " " polypropylene~~
SITE 6 - Prolene " " " " polypropylene
SITE 5 - PVDF : " " " " polyvinylidene fluoride

JHB 7/8/92

7/8/92

| Sample | IV/dl/g |
|---|---|
| NOVAFIL SITE 2 | 0.84 |
| ETHILON SITE 3 | 1.07 |

Robin R. Rayland NB 2519-50

Insufficient sample for prolene IV

| SAMPLE | ~~IV/dl/g~~ MW | MN | MW/MN |
|---|---|---|---|
| NOVAFIL site 2 | 32,000 | 18,000 | 1.8 |
| ETHILON site 3 | 57,000 | 27,000 | 2.1 |

Robin R. Rayland NB 2519-52

| | Mw | MN | | Mw | MN |
|---|---|---|---|---|---|
| Prolene Site 1 | 322,000 | 69,000 | Current 4/0 | 324,000 | 60,000 |
| Prolene Site 6 | 323,000 | 63,000 | | | |

C-23-92 Pg

CONCLUSIONS/COMMENTS:
Comparison of 7 year explants to current 4/0 Prolene sutures indicates no significant degradation

REF. IR & GC 34003
2562-94

| ANALYST | DATE | ANALYST | DATE | SECTION MANAGER | DATE |
|---|---|---|---|---|---|
| Eugene Muse | 10/9/92 | Robin R. Rayland | 9/21/92 | | |
| ANALYST/SUPERVISOR | DATE | ANALYST/SUPERVISOR | DATE | DEPT MANAGER | DATE |
| | | Eugene Muse | 9/21/92 | | |

FL40.206 (Rev. 4/85)

SAMPLE CONTROL # J 2095

# ETHICON, INC.

## ANALYTICAL CHEMISTRY DEPARTMENT

SERVICE REQUEST # 33853

Samples to Gene Muse → Dan Burkley

Pg 1 of 2

| REQUESTOR | DEPARTMENT | EXT. | DATE SUBMITTED | PROJECT NO. | REQUESTOR'S MANAGER AUTHORIZATION |
|---|---|---|---|---|---|
| VISH AGARWAL | 64523 | X2205 | 19th May '92 | 16102 | B. Mattaga |

SAMPLE IDENTIFICATION, SPECIAL STORAGE CONDITIONS, PRECAUTIONS

Samples from Dog # A95 on ERF 85-219 long term Prolene study 6yrs + 10 months

NOVAFIL (site 4) NOVAFIL (site 5) Dog Died prematurely
ETHILON (site 6) PROLENE (site 3)
PVDF (site 2) ETHILON (site 1)

SAMPLE DISPOSITION

X ATTACHED
0 CONTACT REQ
0 RETURN

SENT TO Burkley

SUPERVISOR/ANALYST M Dumais / Burkley Muse

ANALYSIS REQUESTED/PURPOSE:

IR (GPC) DSC OM % ; PPM
NMR TLC (IV) TGA HSM 0, H,O ETO
MS LC XRD TMA SEM DYE MONO
U/V WET DEN DMA EDXA CRYST COMP

OTHER.

See attached protocol

See SR 33788 for SEM

NO. SAMPLES 6

RESULTS: OM + IR Microspectroscopy (for SEM, see SR 33788) – IR microspectroscopy was performed on representative samples that exhibited surface cracking. The following samples were examined by IR microspectroscopy:

NOVAFIL (SITE 4) } For these samples, the explant was examined and
ETHILON (SITE 1) } pictured by OM prior to examining by IR microspectroscopy

PROLENE (SITE 3) → This sample was examined by IR microspectroscopy without any sample preparation - after which it was gold coated and examined by SEM (see SR 33788).

IR spectra obtained from IR microspectroscopy show no differences when comparing cracked ETHILON with a "control" region of the same explant suture (a region that is NOT cracked or discolored). The same can be said for NOVAFIL as well. HOWEVER, expected oxidation absorbances associated with surface cracking would be masked by the ester carbonyl absorbances inherent in these materials. Evidence of oxidation was observed for the PROLENE explant.

All samples examined and commented on as described above were originally submitted with SR 33788.

5-19-92 R

5/22/92

P.S.

CONCLUSIONS/COMMENTS: Samples must be refrigerated untill tested. Thanks you.

REF.

| ANALYST | DATE | ANALYST | DATE | SECTION MANAGER | DATE |
|---|---|---|---|---|---|
| | 5/22/92 | | | | |
| ANALYST/SUPERVISOR | DATE | ANALYST/SUPERVISOR | DATE | DEPT. MANAGER | DATE |
| | | | | | 9/23/4 |

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ANALYTICAL CHEMISTRY DEPT COPY

SAMPLE CONTROL # J 2095

# ETHICON, INC.

## ANALYTICAL CHEMISTRY DEPARTMENT



| SERVICE REQUEST NO. | ANALYSIS REQUIRED | ANALYTICAL SUPERVISOR |
|---|---|---|
| 33853 | GPC, IR Identity | |

TEST REPORT

The explanted samples were prepared as hot pressed films for IR identity. From the IR spectra generated, the explant samples are identified as:

ERF 85-219 Dog 1995

- SITE 1 : ETHILON (Nylon 6)
- SITE 2 : PVDF (polyvinylidene fluoride)
- SITE 3 : Prolene (polypropylene)
- SITE 4 : Novafil (polybutylene terephthalate - polybutoxyether)
- SITE 5 : Novafil ( " - " )
- SITE 6 : ETHILON (Nylon 6)

Jam[illegible] 6/15/92

IR file 33853

| Sample | IV/dlg |
|---|---|
| Novafil (Site 4) | 0.73 |
| Novafil (Site 5) | 0.82 |
| ETHILON (site 1) | 1.25 |
| ETHILON (site 6) | 1.24 |

Robin R Ray/amb NB 2519-31

Insufficient sample for prolene IV's

| Sample | MW | MN | MW/MN |
|---|---|---|---|
| Novafil (site 4) | 32,000 | 18,000 | 1.8 |
| Novafil (site 5) | 33,000 | 18,000 | 1.8 |
| ETHILON (site 1) | 62,000 | 30,000 | 2.1 |
| ETHILON (site 6) | 61,000 | 31,000 | 2.0 |

Robin R Ray/amb NB 2519-34

Although there was insufficient sample to run IV GPC of Dog # 1995 Site 3 was compared to a current 4/0 Prolene suture

| | Mw | MN | N |
|---|---|---|---|
| Dog #1995 Site 3 | 327,000 | 59,000 | |
| Current 4/0 Prolene | 324,000 | 60,000 | |

Results indicate no degradation has taken place EPM 2362-94

| ANALYST SIGNATURE | DATE | REFERENCE |
|---|---|---|
| Robin R Ray/amb | 9/21/92 | |
| SUPERVISOR SIGNATURE | DATE | ANALYTICAL DEPT MANAGER / DATE |
| | | |

SAMPLE CONTROL # J6542

# ETHICON

## ANALYTICAL CHEMISTRY DEPARTMENT

SERVICE REQUEST # 34180

| REQUESTOR | DEPARTMENT | EXT. | DATE SUBMITTED | PROJECT NO. | REQUESTOR'S MANAGER AUTHORIZATION |
|---|---|---|---|---|---|
| V. AGARWAL | 64523 | X2205 | July 27 '92 | 16102 | |

(DOG 2019) (7 YEAR EXPLANT)

SAMPLE IDENTIFICATION, SPECIAL STORAGE CONDITIONS, PRECAUTIONS

1. Prolene Site 2
2. ETHILON Site 5
3. ETHILON Site 6
4. NOVAFIL site 1
5. PVDF Site 4

Size 5-0 samples
DOG # 2019
7 year explant
samples for 10 year
Prolene BSR study

ANALYSIS REQUESTED/PURPOSE

| | | | | | | |
|---|---|---|---|---|---|---|
| IR | GC | GPC | DSC | OM | % : PPM | |
| NMR | TLC | IV | TGA | HSM | 0, | $H_2O$ ETO |
| MS | LC | XRD | TMA | SEM | DYE | MONO |
| U/V | WET | DEN | DMA | EDXA | CRYST | COMP |

OTHER

SEM + OM DATA DOCUMENTED ON SR 34097

NO SAMPLES

SAMPLE DISPOSITION

0 ATTACHED
0 CONTACT REQ.
0 RETURN

SENT TO DFB

SUPERVISOR/ANALYST MUSE BURKLEY ~~LINDEMANN~~ 92

TEST REPORT

Samples prepared as hot-pressed films using the hot stage:

Dog 2019, SITE 1: IR spectrum corresponds to Novafil
SITE 2: IR spectrum corresponds to PROLENE
SITE 3: " " " " PROLENE
SITE 4: " " " " PVDF
SITE 5: " " " " ETHILON
SITE 6: " " " " ETHILON

insufficient sample for prolene IV

8/5/92

| SAMPLE | IV \| dlg |
|---|---|
| ETHILON SITE 5 | 1.00 |
| ETHILON SITE 6 | 1.16 |
| NOVAFIL SITE 1 | 0.87 |

Robin Rayland NB 2519-69

Insufficient sample for prolene IV

| Sample | MW | MN | MW/MN |
|---|---|---|---|
| ETHILON SITE 5 | 92,000 | 21,000 | 3.4 |
| ETHILON site 6 | 74,000 | 22,000 | 3.3 |
| NOVAFIL site 1 | 32,000 | 13,000 | 2.4 |

Robin Rayland NB 2519-71

7-28-92

| | Mw | Mn |
|---|---|---|
| Current Prolene 4/0 | 324,000 | 60,000 |
| Dog #2019 Site 3 | 331,000 | 64,000 |
| Dog# 2019 Site 2 | 332,000 | 57,000 |

CONCLUSIONS/COMMENTS

Comparison of 7 year explants to current prolene indicate no molecular weigh degradation

REF IR file 34180
2562-94

| ANALYST | DATE | ANALYST | DATE | SECTION MANAGER | DATE |
|---|---|---|---|---|---|
| | 8/5/92 | Robin R. Rayland | 9/21/92 | | |
| ANALYST/SUPERVISOR | DATE | ANALYST/SUPERVISOR | DATE | DEPT. MANAGER | DATE |
| Eugene Muse | 10/9/92 | Eugene Muse | 9/21/92 | | |

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SAMPLE CONTROL # I 2261

# ETHICON, INC.
## ANALYTICAL CHEMISTRY DEPARTMENT

SERVICE REQUEST # 34066

| REQUESTOR | DEPARTMENT | EXT. | DATE SUBMITTED | PROJECT NO. | REQUESTOR'S MANAGER AUTHORIZATION |
|---|---|---|---|---|---|
| V. AGARWAL | 64523 | 2205 | July 2'92 | 16102 | |

SAMPLE IDENTIFICATION, SPECIAL STORAGE CONDITIONS, PRECAUTIONS

7 Year Explant Samples from 10-Year Prolene BSR study
Size 5-0
DOG # 2008
(1) Prolene Site #2
(2) PVDF Site #6
(3) ETHILON Site #5
(4) PVDF Site #4 (5) NOVAFIL Site #3
(6) ETHILON Site #1

ANALYSIS REQUESTED/PURPOSE

| | | | | | | |
|---|---|---|---|---|---|---|
| IR | GC | GPC | DSC | OM | % : PPM | |
| NMR | TLC | IV | TGA | HSM | $O_2$ | $H_2O$ ETO |
| MS | LC | XRD | TMA | SEM | DYE | MONO |
| U/V | WET | DEN | DMA | EDXA | CRYST | COMP |

OTHER:

SAMPLE DISPOSITION

| | SENT TO | SUPERVISOR/ANALYST |
|---|---|---|
| 0 ATTACHED | | McVey Barbolt Muse |
| 0 CONTACT REQ | | |
| 0 RETURN | | |

NO. SAMPLES

P.S. Please Keep the samples refrigerated until tested

TEST REPORT: FOR IR Identity, a sample of each explant was hot-pressed into a film on the hot stage, followed by IR examination.

SITE 1 - ETHILON: IR spectrum obtained corresponds to Nylon 6
SITE 2 - PROLENE: " " " " polypropylene
SITE 3 - Novafil: " " " " polybutyleneterephthalate-polybutyleneether
SITE 4 - PVDF: " " " " polyvinylidene fluoride
SITE 5 - ETHILON: " " " " Nylon 6
SITE 6 - PVDF: " " " " polyvinylidene fluoride

all IR spectra verify the identity of the sutures isolated.
7/9/92 Vasant A. Patel

| SAMPLE | IV/dl/g | | MW | MN |
|---|---|---|---|---|
| ETHILON #1 | # 0.95 | Dog # 2008 Site 2 | 322,000 | 53,000 |
| ETHILON #5 | 1.28 | Current Prolene 4/0 | 324,000 | 60,000 |
| NOVAFIL #3 | 0.79 | Robin R. Rayborn NB 2519-50 | | 2562-94 |

Insufficient sample for prolene IV

| SAMPLE | MW | MN | MW/MN |
|---|---|---|---|
| ETHILON site #1 | 53,000 | 27,000 | 2.0 |
| ETHILON site #5 | 59,000 | 28,000 | 2.1 |
| NOVAFIL site #3 | 32,000 | 18,000 | 1.8 |

Robin R. Rayborn NB 2519-52 7-2-92

CONCLUSIONS/COMMENTS:
Comparison of current prolene 4/0 sutures indicates no significant degradation of 7 yr explant

REF IR fil 34066

| ANALYST | DATE | ANALYST | DATE | SECTION MANAGER | DATE |
|---|---|---|---|---|---|
| Vasant A. Patel | 7/11/92 | Robin R. Rayborn | 9/24/92 | | |
| ANALYST/SUPERVISOR | DATE | ANALYST/SUPERVISOR | DATE | DEPT. MANAGER | DATE |
| Eugene Muse | 10/9/92 | Eugene Muse | 9/24/92 | | |

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ACCESSION 85-219

PROJECT NO. 16102

EXPLANTATION PROCEDURES and SAMPLE DISTRIBUTION

Notify the following people of upcoming explant dates:

Nancy Myirski, x2743: Microscopic inspection - someone from her group will come to inspect the sutures under the dissecting scope under the hood. Samples should be placed after dissection from dog into saline-moistened paper towels labelled with the ERF acc. no., dog no., site no., suture type and date. (Ann Leibold was inspector @ 2 yr. time period, 6/87)

Frank Schiller, x3040: SEM - An Analytical Chemistry Service Request form must be filled out and accompany each set of samples.* Put the sample control number on the top left corner of the sample label. Make one copy for our file and one to send with the samples. Mail original to Dr. A. Melvegar. Label samples the same as for above.

Implantation (Stef or Don?)
~~Kevin Sullivan, x2997:~~ Instron - Submit samples after the microscopic inspection, while moist. Fragments are saved in their respective towels for next tests. Refrigerate if there will be a delay between inspection and instroning.

Gene Muse, x3046: Molecular weight - Deliver moist suture fragments after Instroning. After testing he will deliver samples to Dan.

Dan Burkley, x3048: I.R. - Receives samples from Gene. Will discard samples when testing is completed.

Explant samples in consecutive order. Dissect both LC100's (dorsal and ventral) from surrounding connective tissue, carefully stripping tissue from the suture surface. Cut one of the LC100's off the sutures at the clip and gently pull the suture bundle through the tissue by gripping the remaining LC100. When free of tissue, moisten with saline and separate one strand from the bundle. Place this strand into a large (15 ml) red-top tube filled with sterile water and labelled as described above. The other 5 strands per bundle are placed in moistened paper towels labelled as described above. The single sutures in tubes are submitted for SEM and the remaining strands are inspected microscopically and tested on the Instron, etc. as described above.

* 2 request forms per dog: - 1 for SEM + OM + IR microscopy for the samples going to J. McVey
- 1 for IR, GPC + IV for the fragments going to G. Muse + D. Burkley

Have JOP sign each + send to A. Melvegar.